UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC. Defendant.	C.A. No. 06-222 (JJF) **REDACTED - PUBLIC VERSION**

JOINT PRETRIAL ORDER

1. Pursuant to D. Del. LR 16.3(c), Plaintiff Wyeth ("Wyeth") and Defendant Impax Laboratories, Inc. ("Impax"), by their undersigned counsel, submit this proposed Joint Pretrial Order in anticipation of the Pretrial Conference scheduled for January 10, 2008 at 12:30 PM.

I. NATURE OF THE ACTION

2. This is a civil action for patent infringement. It arises out of Impax's submission of Abbreviated New Drug Application ("ANDA") No. 78-057 to the United States Food and Drug Administration ("FDA").

3. Under the trade name Effexor® XR, Wyeth sells extended-release capsules that contain venlafaxine hydrochloride ("HCl") as the active drug component. Effexor® XR is used in the treatment of, *inter alia*, depression and certain anxiety disorders.

4. Through ANDA No. 78-057, Impax sought approval from the FDA to market generic versions of Wyeth's Effexor® XR Capsules prior to the expiration of Wyeth's United States Patent Nos. 6,274,171 B1 ("the '171 patent"); 6,403,120 B1 "(the '120 patent"); and 6,419,958 B2 ("the '958 patent"). Specifically, Impax sought FDA approval for the commercial manufacture, use, or sale of Venlafaxine HCl Extended-Release Capsules in 37.5, 75, and

150 mg dosage strengths.

5. By letter dated February 21, 2006, Impax sent notice to Wyeth of Impax's ANDA filing, and included a Paragraph IV certification alleging that the '171 patent, the '120 patent and the '958 patent were not infringed by Impax's generic products. Within forty-five days of receiving Impax's notice, Wyeth filed suit against Impax, asserting infringement of the '171 patent, the '120 patent, and the '958 patent (collectively, "the patents in suit").

6. In its Complaint (D. I. l), Wyeth alleges that, under 35 U.S.C. § 271(e)(2)(A), Impax's submission of ANDA No. 78-057 to the FDA constituted an act of infringement of the patents in suit, either literally or under the doctrine of equivalents. Wyeth also alleges that, upon approval of ANDA No. 78-057, Impax will infringe the patents in suit, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, or importing its Venlafaxine HCl Extended-Release Capsules in the United States and by actively inducing and contributing to infringement by others under 35 U.S.C.§§ 271(b) and (c) unless this Court orders that the effective date of any FDA approval of ANDA No. 78-057 shall be no earlier than the latest expiration date of the patents in suit and any additional periods of exclusivity.

7. In response to Wyeth's Complaint, Impax filed a series of Answers and Counterclaims. Currently, Impax's operative responsive pleading is its Second Amended Answer, Affirmative Defenses, Counterclaims and Prayer for Relief. (D.I. 186). In its responsive pleadings, Impax denied infringement of the patents in suit, and alleged as a defense that the patents in suit are invalid and unenforceable. Additionally, Impax asserted counterclaims for declarations that (a) its Venlafaxine HCl Extended-Release Capsules do not infringe the patents in suit and (b) the patents in suit are invalid and unenforceable.

8. Wyeth has filed a Reply to Impax's Second Amended Answer, Affirmative Defenses, Counterclaims and Prayer for Relief denying that Impax's Venlafaxine HCl Extended-Release Capsules do not infringe the patents in suit and denying that the patents in suit are invalid or unenforceable. (D.I. 213).

II. BASIS OF FEDERAL JURISDICTION

9. This action arises under the patent laws of the United States, 35 U.S.C. §§ 101, et seq., including 35 U.S.C. § 271(b), (c), and (e)(2).

10. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. Venue is proper in this District under 28 U.S.C. §§ 1391(c) and 1400(b).

12. The Court has personal jurisdiction over the parties.

III. FACTS THAT HAVE BEEN ADMITTED

13. A statement of the facts that are admitted and require no proof is set forth at Tab A.

IV. ISSUES OF FACT THAT REMAIN TO BE LITIGATED

14. Wyeth's Statement of Issues of Fact That Remain To Be Litigated is attached at Tab B.

15. Impax's Statement of Issues of Fact That Remain To Be Litigated is attached at Tab C.

16. If any statement in a party's Statement of Issues of Fact That Remain To Be Litigated should properly be considered an issue of law, then such statement shall be considered to be part of the party's Statement of Issues of Law That Remain To Be Litigated.

17. The parties reserve the right to modify or supplement their Statements of Issues of Fact That Remain To Be Litigated to the extent necessary to fairly reflect the Court's rulings on any pending motions.

V. ISSUES OF LAW THAT REMAIN TO BE LITIGATED

18. Wyeth's Statement of Issues of Law That Remain To Be Litigated is attached at Tab D.

19. Impax's Statement of Issues of Law That Remain To Be Litigated is attached at Tab E.

20. If any statement in a party's Statement of Issues of Law That Remain To Be Litigated should properly be considered an issue of fact, then such statement shall be considered to be part of the party's Statement of Issues of Fact That Remain To Be Litigated.

21. The parties reserve the right to modify or supplement their Statements of Issues of Law That Remain To Be Litigated to the extent necessary to fairly reflect the Court's rulings on any pending motions.

VI. LIST OF EXHIBITS

22. Wyeth's List of Exhibits that Wyeth may introduce at trial, including Impax's objections thereto, is attached at Tab F.

23. Impax's List of Exhibits that Impax may introduce at trial, including Wyeth's objections thereto, is attached at Tab G.

24. The parties have made a good-faith effort to set forth a complete list of exhibits upon which they may rely at trial; however, the parties reserve the right to supplement these exhibit lists up to 20 days prior to commencement of trial. Except for exhibits that are to be used solely for impeachment, a party may not introduce at trial any exhibit not appearing on its list or not appearing on the other party's list, unless the Court determines that the interests of justice so warrant.

25. Demonstrative exhibits need not be listed on the parties' Exhibit lists. Except as provided for in paragraph 26 below, the parties shall exchange demonstrative exhibits in hardcopy form by 7:00 PM one calendar day before their anticipated use. The notice provisions of this paragraph will not apply to demonstrative exhibits used in opening or closing statements, if the Court entertains such statements. The parties shall exchange demonstrative exhibits used in opening or closing statements at least 30 minutes before those statements begin.

26. The notice provisions of paragraph 25 will not apply to demonstrative exhibits

created in the courtroom during testimony or to demonstrative exhibits that are merely excerpts, enlargements, or highlights of trial exhibits.

27. Each party may use an exhibit that is listed on the other side's exhibit list, to the same effect as though it were listed on its own exhibit list, subject to evidentiary objections. The listing of a document on a party's list is not an admission that such document is relevant or admissible when offered by the opposing party for the purpose that the opposing party wishes to admit the document. Any exhibit, once admitted, may be used equally by each party for any proper purpose.

VII. LIST OF WITNESSES

28. Wyeth's List of Witnesses is attached at Tab H. The list contains the names of all the witnesses that Wyeth intends to call to testify (including employees of the opposing party), as well as all witnesses that Wyeth may call to testify, and identifies whether the witness will testify in person or by deposition.

29. Impax's List of Witnesses is attached at Tab I. The list contains the names of all the witnesses that Impax intends to call to testify (including employees of the opposing party), as well as all witnesses that Impax may call to testify, and identifies whether the witness will testify in person or by deposition.

30. The listing of a witness on a party's witness list does not require that party to call that witness to testify, either in person or by deposition, or to bring that witness to trial.

31. Pursuant to the Court's Trial Management Order, each party's List of Witnesses includes the required information for witnesses whom the calling party may seek to have testify in rebuttal on issues for which the calling party has the burden of proof.

32. No witness called by a party shall be permitted to testify at trial unless identified on that party's List of Witnesses, unless the Court determines that the interests of justice so warrant.

33. The parties shall exchange designations of the deposition testimony that they

intend to offer at trial on Monday, January 14, 2008. The opposing party shall provide objections and counter-designations on or before Monday, January 28, 2008. The original designating party shall provide objections to counter-designations on or before Monday, February 4, 2008. Except by agreement of the parties or by leave of Court, no other deposition designations may be introduced at trial.

34. When deposition designations are introduced, all counter-designations will also be introduced in the sequence in which the testimony was originally given. To the extent that deposition designations are read or played at trial, each party will be charged for the time taken to read or play its designations, as measured by the proportion of lines of testimony each party designated to the total number of lines of testimony read or played.

35. By 7:00 PM two calendar days before a witness will be called to testify live or by deposition, the calling party will provide notice to the opposing party of the name of the witness that will be called. Each party will give 48 hours notice of when it intends to complete the presentation of its evidence. Not more than 12 hours after receiving such notice, the opposing party will identify the witness (or witnesses) that it intends to call on its first day of its case in chief or rebuttal.

VIII. BRIEF STATEMENT OF INTENDED PROOF

36. Wyeth's Brief Statement of Intended Proof is attached at Tab J.

37. Impax's Brief Statement of Intended Proof is attached at Tab K.

IX. AMENDMENT OF THE PLEADINGS

38. On September 11, 2007 the parties filed a stipulation regarding Impax's request for leave to file its proposed "Third Amended Answer, Affirmative Defenses, Counterclaims and Prayer for Relief" (D.I. 262). If the stipulation is granted, Wyeth will be allowed to file a Reply or otherwise respond within twenty court days of entry of an order permitting Impax to file its Third Amended pleading. (*Id.*).

X. CERTIFICATE OF ATTEMPTED RESOLUTION

39. The parties certify that they have engaged in a good-faith effort to explore the resolution of their controversy by settlement, but have been unsuccessful to date.

XI. MISCELLANEOUS ISSUES

40. Subject to the Court's approval, the parties agree that each side be allowed a one hour opening statement.

41. Wyeth's List of Miscellaneous Issues is attached at Tab L.

42. Impax's List of Miscellaneous Issues is attached at Tab M.

43. This Order shall control the subsequent course of the action, unless modified by the Court to prevent manifest injustice. D. Del. LR 16.3(d)(4).

Dated: January 3, 2008

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SO ORDERED.

Dated:

The Honorable Joseph J. Farnan, Jr.
UNITED STATES DISTRICT JUDGE

EXHIBIT A

TAB A

Statement of Admitted Facts

The following facts have been admitted and, thus, require no proof at trial:

1. Wyeth is a Delaware corporation with its principal place of business at Five Giralda Farms, Madison, New Jersey 07940.

2. Impax is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

3. Impax has a place of business at 3735 Castor Avenue, Philadelphia, Pennsylvania 19124.

4. Impax has appointed a registered agent in Delaware for service of process.

5. Wyeth is the holder of New Drug Application No. 20-699 for Effexor® XR Capsules.

6. Under 21 U.S.C. § 355(j), Impax filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") that was assigned No. 78-057. ANDA No. 78-057 was filed to obtain approval for the commercial manufacture, use, and sale of Venlafaxine HCl Extended-Release Capsules in 37.5, 75, and 150 mg dosage strengths.

7. Impax is seeking approval to make, use, and sell generic versions of Wyeth's Effexor® XR Capsules in 37.5, 75, and 150 mg dosage strengths.

8. In a letter dated February 21, 2006, Impax notified Wyeth that Impax had filed an ANDA seeking approval to market Venlafaxine HCl Extended-Release Capsules in 37.5, 75, and 150 mg dosage strengths, and that Impax was providing information to Wyeth pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95.

9. The '171 patent, which is entitled "Extended Release Formulation of Venlafaxine Hydrochloride," issued on August 14, 2001.

10. The '171 patent lists Deborah M. Sherman, John C. Clark, John U. Lamer, and Steven A. White as inventors.

11. Wyeth is the owner by assignment of the '171 patent and has the right to sue for

infringement of that patent.

12. Impax filed ANDA No. 78-057 to obtain approval to market its Venlafaxine HCl, Extended-Release Capsules in the United States before the expiration of the '171 patent.

13. ANDA No. 78-057 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), which alleges that the claims of the '171 patent will not be infringed.

14. The '120 patent, which is entitled "Extended Release Formulation of Venlafaxine Hydrochloride," issued on June 11, 2002.

15. The '120 patent lists Deborah M. Sherman, John C. Clark, John U. Lamer, and Steven A. White as inventors.

16. Wyeth is the owner by assignment of the '120 patent and has the right to sue for infringement of that patent.

17. Impax filed ANDA No. 78-057 to obtain approval to market its Venlafaxine HCl Extended-Release Capsules in the United States before the expiration of the '120 patent.

18. ANDA No. 78-057 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), which alleges that the claims of the '120 patent will not be infringed.

19. The '958 patent, which is entitled "Extended Release Formulation of Venlafaxine Hydrochloride," was issued on July 16, 2002.

20. The '958 patent lists Deborah M. Sherman, John C. Clark, John U. Lamer, and Steven A. White as inventors.

21. Wyeth is the owner by assignment of the '958 patent and has the right to sue for infringement of that patent.

22. Impax filed ANDA No. 78-057 to obtain approval to market its Venlafaxine HCl Extended-Release Capsules in the United States before the expiration of the '958 patent.

23. ANDA No. 78-057 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), which alleges that the claims of

the '958 patent will not be infringed.

24. The generic name for Effexor® XR is venlafaxine hydrochloride extended-release capsules.

25. The active ingredient in Effexor® XR is venlafaxine hydrochloride.

26. Effexor® XR is encapsulated.

27. The label for Wyeth's Effexor® XR product states that "Effexor XR is formulated as an extended-release capsule for once-a-day oral administration."

28. The label for Wyeth's Effexor® XR product states that "Effexor® XR (venlafaxine hydrochloride) extended-release capsules is indicated for the treatment of major depressive disorder."

29. The label for Wyeth's Effexor® XR product states that "Effexor® XR is indicated for the treatment of Social Anxiety Disorder, also known as Social Phobia, as defined in DSM-IV (300.23)."

30. The label for Wyeth's Effexor® XR product states that "Effexor® XR is indicated for the treatment of Generalized Anxiety Disorder (GAD) as defined in DSM-IV."

31. The label for Wyeth's Effexor® XR product states that "Effexor® XR is indicated for the treatment of panic disorder, with or without agoraphobia, as defined in DSM-IV."

32. The label for Wyeth's Effexor® XR product states that "Administration of Effexor® XR (150 mg q 24 hours) generally resulted in lower Cmax (150 mg/mL for venlafaxine and 260 mg/mL for ODV) and later Tmax (5.5 hours for venlafaxine and 9 hours for ODV) than for immediate release venlafaxine tablets . . . ."

33. The label for Wyeth's Effexor® XR product states that "drug release is controlled by diffusion through the coating membrane on the spheroids and is not pH dependent."

34. Impax filed ANDA No. 78-057 with the FDA seeking approval to market a generic version of Effexor® XR.

35. The active ingredient in the Impax Venlafaxine HC1 Extended-Release Capsules that are the subject of ANDA No. 78-057 is venlafaxine hydrochloride.

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46. REDACTED

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48. The '171, '120, and '958 patents (collectively "the patents in suit") share essentially the same specification.

49. REDACTED

50. U.S. Patent No. 4,535,186 ("the '186 patent"), which is entitled "2-Phenyl-2-(1-Hydroxycycloalkyl or 1-Hydroxycycloalk-2-enyl)Ethylamine derivatives," issued on August 13, 1985.

51. The '186 patent lists G. E. Morris Husbands, John P. Yardley, and Eric A. Muth as inventors.

52. Wyeth is the owner by assignment of the '186 patent.

53. The '186 patent disclosed venlafaxine, (±)-1-[2-(Dimethylamino)-1-(4-methoxyphenyl)ethyl]cyclo-hexanol, as one of numerous chemical compounds disclosed in the '186 patent.

54. Wyeth's formulation of immediate-release venlafaxine hydrochloride was approved for sale in the United States on December 28, 1993.

55. U.S. Patent No. 4,138,475 ("the '475 patent"), which is entitled "Sustained Release Pharmaceutical Composition," issued on February 6, 1979.

56. The '475 patent lists James McAinsh and Raymond C. Rowe as inventors.

57. U.S. Patent No. 5,506,270 ("the '270 patent"), which is entitled "Venlafaxine In The Treatment Of Hypothalamic Amenorrhea In Non-Depressed Women," issued on April 9, 1996.

58. The '270 patent lists Gertrude V. Upton, Albert T. Derivan, and Richard L. Rudolph as inventors.

59. The patent application that led to the '270 patent was filed on January 30, 1995.

60. Wyeth is the owner by assignment of the '270 patent.

61. International application No. WO 94/27589 ("the '589 application"), which is entitled "Antidepressant Dosage Form," was published on December 8, 1994.

62. The '589 application lists David E. Edgren, Gurdish Kaur Bhatti, Zahedeh Hatamkhani, and Patrick S.-L. Wong as inventors.

63. International application No. WO 92/01446 ("the '446 application"), which is entitled "Sustained-Release Formulations," was published on February 6, 1992.

64. The '446 application lists Brian William Barry, Bryan Arthur Mulley, and Peter York as inventors.

65. REDACTED

66. REDACTED

67. REDACTED

68. REDACTED

69. REDACTED

REDACTED

70. REDACTED

REDACTED

71. Wyeth conducted clinical trials in order to gain FDA approval for Effexor® XR.

72. REDACTED

REDACTED

73. REDACTED

REDACTED

74. REDACTED

REDACTED

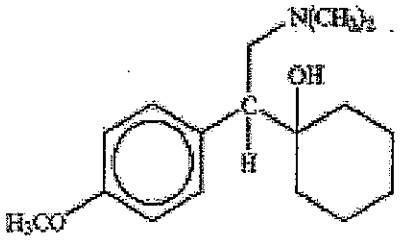
75. U.S. Patent 6,440,457 ("the '457 patent"), which is entitled "Method of Administering Antidepressant Dosage Form," issued on August 27, 2002.

76. The '457 patent lists David Emil Edgren, Gurdish Kaur Bhatti, Zahedeh Hatamkhani, and Patrick S.-L. Wong as inventors.

77. The '457 patent states on its face that it is assigned to Alza Corporation.

78. The '457 patent's single claim, claim 1, states:

1. A method for administering a drug to the gastrointestinal tract of a human, wherein the method comprises: (a) admitting orally into the human a dosage form comprising a drug of the formula:



which drug possess antidepressant therapy and the dosage form comprises a member selected from the group consisting of a sustained-release dosage form and a controlled-release dosage form; and, (b) administering the drug from the dosage form over an extended period of time in a therapeutically responsive dose to produce the antidepressant therapy.
'457 patent, claim 1.

79. Alza asserted the '457 patent against Wyeth, claiming that Effexor® XR infringed claim 1 of that patent.

80. U.S. Patent No. 4,111,201 ("the '201 patent"), which is entitled "Osmotic System For Delivering Selected Beneficial Agents Having Varying Degrees Of Solubility," issued on September 5, 1978.

81. The '201 patent lists Felix Theeuwes as the inventor.

82. U.S. Patent No. 4,761,501 ("the '501 patent"), which is entitled "Substituted Phenylacetamides," issued on August 2, 1988.

83. The '501 patent lists G. E. Morris Husbands, John P. Yardley, and Eric A. Muth as inventors.

84. The '501 patent issued from Application No. 736,744, which is a divisional of Application No. 545,701.

85. Wyeth is the owner by assignment of the '501 patent.

86. The '186 patent issued from Application No. 545,701.

87. The PTO ordered the Reexamination of the '457 patent.

EXHIBIT B

TAB B

Wyeth's Statement of Issues of Fact That Remain to Be Litigated

Wyeth reserves the right to modify, supplement, or change this Statement of Issues of Fact That Remain to Be Litigated to the extent necessary to fairly reflect the Court's rulings on any pending motions. Wyeth also reserves the right to modify, supplement, or change this Statement of Issues of Fact That Remain to Be Litigated to the extent necessary to fairly respond to any issues that Impax raises or drops in its Statement of Issues of Fact That Remain to Be Litigated.

If any statement in Wyeth's Statement Of Issues of Fact That Remain To Be Litigated should properly be considered an issue of law, then such statement shall be considered to be part of Wyeth's Statement of Issues of Law That Remain To Be Litigated.

I. INFRINGEMENT

The parties will litigate the questions of:

1. Whether the administration or use by health care professionals or patients of Impax's proposed venlafaxine HCl extended-release capsules that are the subject of ANDA No. 78-057 in accordance with the proposed labeling would literally meet each properly construed claim limitation of claims 20-25 of United States Patent No. 6,274,171 B1, claims 1, 2, 13, and 14 of United States Patent No. 6,403,120 B1, and claims 1-6 of United States Patent No. 6,419,958 B2? (Literal Infringement)

2. For any properly construed claim limitation that Impax argues is not met literally as claimed, whether the administration or use by health care professionals or patients of Impax's venlafaxine HCl extended-release capsules that are the subject of ANDA No. 78-057 in accordance with the proposed labeling would meet those claim limitations under the doctrine of equivalents? (Infringement Under the Doctrine of Equivalents). In light of Impax's Brief

Statement of What It Intends to Prove at Trial, it does not appear that Impax is contesting literal infringement under the Court's December 13, 2007 claim construction. D.I. 315. Wyeth submits that the claim construction ruling renders the issue of infringement under the doctrine of equivalents moot.

3. Whether Impax's offering to sell, selling, or importing the venlafaxine HCl extended-release capsules that are the subject of ANDA No. 78-057 would actively induce infringement of claims 20-25 of United States Patent No. 6,274,171 B1, claims 1, 2, 13, and 14 of United States Patent No. 6,403,120 B1, and claims 1-6 of United States Patent No. 6,419,958 B2?

4. Whether Impax's offering to sell, selling, or importing the venlafaxine HCl extended-release capsules that are the subject of ANDA No. 78-057 would render Impax liable as a contributory infringer of claims 20-25 of United States Patent No. 6,274,171 B1, claims 1, 2, 13, and 14 of United States Patent No. 6,403,120 B1, and claims 1-6 of United States Patent No. 6,419,958 B2?

II. VALIDITY

The parties will litigate whether Impax has presented clear and convincing evidence to establish invalidity or unenforceability. The underlying factual issues related to these defenses are as follows:

A. Anticipation

1. Does International Publication No. WO 94/27589 ("'589 publication") necessarily and inevitably disclose, expressly or inherently, each and every properly construed limitation of the asserted claims, and does its description enable one with ordinary skill in the relevant art to understand and make the claimed invention?

REDACTED

B. Obviousness

2. What was the scope and content of the prior art?

3. What are the differences between the prior art and the asserted claims?

4. What was the level of ordinary skill in the relevant art?

5. What objective indicia of non-obviousness are present?

6. Whether the differences between the asserted claimed inventions and the prior art are such that the claimed inventions as a whole would have been obvious at the time the inventions were made to a person having ordinary skill in the art to which the claimed inventions pertain?

7. Whether at the time the inventions were made one with ordinary skill in the relevant art would have had a reasonable expectation of success in developing venlafaxine hydrochloride into a once-a-day extended release formulation that would be therapeutically effective?

8. Whether at the time the inventions were made one with ordinary skill in the relevant art would have had a reasonable expectation of success in developing venlafaxine hydrochloride into a once-a-day extended release formulation that would result in a diminished incidence of nausea and vomiting?

9. Does the practice of the methods of the asserted claims result in diminished incidences of nausea and emesis as compared to the use of immediate release formulations of venlafaxine hydrochloride, and would such diminished incidences of nausea and emesis have been unexpected to one of ordinary skill in the art at the time the inventions of the asserted claims were made?

10. Was there initial skepticism regarding whether the claimed invention would have diminished side effects compared to immediate-release venlafaxine?

11. Did the claimed invention satisfy a long-felt need in the arsenal of prescription antidepressants and anxiolytics available in the market?

12. Was the subject matter of the asserted claimed inventions a commercial success, and is there a nexus between the claimed inventions and that success?

13. Does Impax's copying of the asserted claimed inventions further support a finding of non-obviousness?

14. Does the objective evidence of non-obviousness presented by Wyeth, including unexpected diminished incidences of nausea and emesis, long felt need, skepticism, evidence of copying, and/or commercial success, preclude a finding of obviousness?

C. Written Description

15. Would one skilled in the relevant art, considering the specifications of the patents-in-suit in their entirety, including the original claims, recognize that the disclosure of the patents-in-suit demonstrates that the inventors had in their possession the inventions of the asserted claims?

D. Enablement

16. Whether a person of ordinary skill in the relevant art, using the knowledge available to such a person and the disclosure in the patent specifications, could make and use the claimed inventions without undue experimentation?

E. Inventorship

REDACTED

F. Indefiniteness

18. Whether, in light of the Court's December 13, 2007 construction of the phrase, "eliminating the troughs and peaks of drug concentration in a patient's blood plasma . . . attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride," the Court should preclude Impax from asserting that the meaning of the claim term "therapeutic metabolism" is indefinite.

III. ENFORCEABILITY

1. Did any individual at Wyeth who was substantively involved in the preparation or prosecution of the patents-in-suit make any material misrepresentation to the Patent Office during the prosecution of the patents-in-suit with an intent to deceive regarding the statistically significant improvement of venlafaxine ER over conventional venlafaxine hydrochloride tablets?

2. Did any individual at Wyeth who was substantively involved in the preparation or prosecution of the patents-in-suit make any material omission to the Patent Office

during the prosecution of the patents-in-suit with an intent to deceive regarding the Alza PCT application or inventorship?

3. Does the applicants' conduct viewed in light of all the evidence, including evidence of good faith, indicate sufficient culpability to require a finding of intent to deceive?

IV. RELIEF

1. Whether Wyeth is entitled, under 35 U.S.C. § 271(e)(4)(A), to an Order that the effective date of any approval of Impax's proposed venlafaxine HCl extended-release capsules that are the subject of ANDA No. 78-057 be a date not earlier than the latest expiration date of U.S. Patent No. 6,274,171 B1, U.S. Patent No. 6,403,120 B1 and U.S. Patent No. 6,419,958 B2, or any later date of exclusivity to which Wyeth is or becomes entitled?

2. Whether Wyeth is entitled, under 35 U.S.C. § 271(e)(4)(B), to a permanent injunction, restraining or enjoining Impax from engaging in the commercial manufacture, use, offer for sale or sale of its proposed venlafaxine HCl extended-release capsules within the United States, or importation into the United States?

V. ATTORNEYS' FEES

Whether the case is exceptional such that Wyeth is entitled to its attorneys' fees.

EXHIBIT C

IMPAX'S STATEMENT OF ISSUES OF FACT TO BE LITIGATED

The following factual issues remain to be litigated.[1] To the extent that any of the issues of law set forth in Impax's Statement of Issues of Law That Remain to Be Litigated are properly considered issues of fact, Impax incorporates those portions of that Statement herein by reference. To the extent any of the issues set forth in this Statement of Issues of Fact That Remain to Be Litigated are properly considered issues of law, Impax incorporates those portions of this Statement into its Statement of Issues of Law That Remain to Be Litigated.

A. Infringement.

1. Whether Impax's accused extended-release venlafaxine product, if marketed and sold within the United States, would literally infringe any of the asserted claims of the patents-in-suit

2. Whether Impax's accused extended-release venlafaxine product, if marketed and sold within the United States, would infringe any of the asserted claims of the patents-in-suit under the doctrine of equivalents.

3. Whether Impax's accused extended-release venlafaxine product, if marketed and sold within the United States, would indirectly infringe any of the asserted claims of the patents-in-suit by inducing the infringement in the United States of any of those claims by others.

4. Whether Impax's accused extended-release venlafaxine product, if marketed and sold within the United States, would indirectly infringe any of the asserted claims of the patents-in-suit by contributing to the infringement in the United States of any of those claims by others.

B. Invalidity.

5. The level of ordinary skill in the art to which each of the patents-in-suit relates.

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[1] In light of the Court's recent claim-construction ruling, and in order to create a record in case of appeal, Impax also intends to make an offer of proof regarding the evidence it would have presented regarding non-infringement and invalidity had the Court accepted Impax's proffered constructions of the disputed claim terms in the asserted claims of the patents-in-suit. In the interest of completeness, this list contains issues of fact on which Impax intends to make such offers of proof.

6. The scope and nature of the prior art to the asserted claims of the patents-in-suit.

7. The extent to which the limitations of the asserted claims of the patents-in-suit are present in the prior art.

8. Whether any of the asserted claims of the patents-in-suit are invalid under 35 U.S.C. § 102 because they are anticipated by any single piece of prior art.

9. Whether, in developing its extended-release venlafaxine product, Wyeth combined prior art elements according to known methods.

10. Whether, in developing its extended-release venlafaxine product, Wyeth used techniques known to improve similar products in the same way.

11. Whether, in developing its extended-release venlafaxine product, Wyeth applied a known technique to a known product ready for improvement.

12. Whether the results of Wyeth's efforts to develop extended-release venlafaxine were predictable.

13. Whether the claimed benefits of Wyeth's extended-release venlafaxine formulation, including elimination in peaks and troughs associated with multiple daily dosing, time to peak blood-plasma concentration within certain specified time frames, and a reduced side-effect profile, would be inherent benefits of any extended-release venlafaxine formulation.

14. Whether Wyeth faced design need or market pressure in developing its extended-release venlafaxine product.

15. Whether there were a finite number of identified, predictable solutions to the question of developing extended-release venlafaxine.

16. Whether Wyeth reasonably expected to succeed in developing extended-release venlafaxine.

17. Whether some teaching, suggestion, or motivation existed in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

18. Whether any secondary considerations exist that relate to obviousness.

19. If any secondary considerations relating to obviousness exist, whether any of them have a sufficient nexus to any of the inventions described in the claims of the patents-in-suit.

20. Where the specification of the patents-in-suit disclose only extended-release venlafaxine formulations created through extrusion and spheronization and containing three specific ingredients, whether the asserted claims of the patents-in-suit, which have been construed to extend to formulations created by other methods and containing other ingredients, are invalid for failure of the patents-in-suit to provide an adequate written description sufficient to convey to a person of skill in the art that the patentee had possession of the full scope of the claimed invention, including all claim limitations, at the time of the application.

21. Where the specification of the patents-in-suit discloses failed attempts to create extended-release venlafaxine using particular methods and ingredients, whether the asserted claims of the patents-in-suit, which have been construed to extend to extended-release venlafaxine created by such methods or using such ingredients, are invalid for failure of the patents-in-suit to describe the manner and process of making and using the full scope of the claimed invention in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use it.

22. Whether any or all of the claims of the patents-in-suit are invalid for failure of Wyeth to join as an inventor

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23. Whether the phrase "therapeutic metabolism," which is used in the patents-in-suit, has any meaning to persons of ordinary skill in the art.

C. Inequitable conduct.

24. Whether, during the prosecution of the patents-in-suit, Wyeth made material

misrepresentations to the United States Patent and Trademark Office ("PTO") regarding the allegedly statistically-significant improvement offered by extended-release venlafaxine over immediate-release venlafaxine with respect to incidences of nausea, purportedly as demonstrated in three Wyeth clinical studies.

25. Whether Wyeth's material misrepresentations to the PTO regarding the three Wyeth clinical studies were made with intent to mislead the PTO.

26. Whether, during the prosecution of the patents-in-suit, Wyeth failed to disclose material information, including

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27. Whether Wyeth's failure to disclose material information to the PTO regarding REDACTED done with intent to mislead the PTO.

D. Remedies and attorneys' fees.

28. Whether Wyeth is entitled to an order barring Impax from making, using, offering for sale, selling its proposed extended-release venlafaxine product in the United States, or importing that product into the United States.

29. Whether this is an exceptional case entitling Wyeth to its attorneys' fees.

EXHIBIT D

TAB D

Wyeth's Statement of Issues of Law That Remain to Be Litigated

Wyeth reserves the right to modify, supplement, or change this Statement of Issues of Law That Remain to Be Litigated to the extent necessary to fairly reflect the Court's rulings on any pending motions. Wyeth also reserves the right to modify, supplement, or change this Statement of Issues of Law That Remain to Be Litigated to the extent necessary to fairly respond to any issues that Impax raises or drops in its Statement of Issues of Law That Remain to Be Litigated.

If any statement in Wyeth's Statement Of Issues of Law That Remain To Be Litigated should properly be considered an issue of fact, then such statement shall be considered to be part of Wyeth's Statement of Issues of Fact That Remain To Be Litigated.

I. INFRINGEMENT

Wyeth has asserted that the administration or use by health care professionals or patients of the Impax proposed products infringe claims 20-25 of United States Patent No. 6,274,171 B1; claims 1, 2, 13, and 14 of United States Patent No. 6,403,120 B1; and claims 1-6 of United States Patent No. 6,419,958 B2 (hereinafter, "the asserted claims of the patents-in-suit"). Wyeth has the burden of proving infringement by a preponderance of the evidence. *Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1285 (Fed. Cir. 2002).

Pursuant to 35 U.S.C. § 271(e)(2)(A), it is "an act of infringement to submit an [ANDA] for a drug claimed in the patent or the use of which is claimed in the patent . . . ." The Federal Circuit has explained that the focus of an infringement analysis based on an ANDA filing is on the product that is likely to be sold following FDA approval. *Abbott Labs v. Torpharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002); *Glaxo Inc. v. Novapharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997); *Bristol-Myers Squib Co. v. Royce Labs, Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995)

(relevant inquiry is "whether, if a particular drug were put on the market, it would infringe the relevant patents."). Specifically, "[b]ecause drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry." *Abbott Labs*, 300 F.3d at 1373. Consequently, under a traditional infringement analysis, "[i]f an ANDA specification defines a property of a compound such that it must meet a limitation of an asserted claim, then there will almost never be a genuine dispute of material fact that the claim is infringed with respect to that limitation." *Id.*

Issues of claim construction have already been briefed and argued by the parties. The Court issued its Markman ruling on December 13, 2007. "[T]he construction of a patent, including terms of art within its claim, is exclusively within the province of the court." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996).

A. Direct Infringement

Direct infringement can be shown either literally or under the doctrine of equivalents.

1. Literal Infringement

The parties will litigate whether the administration or use of the venlafaxine HCl extended-release capsules that are the subject of ANDA No. 78-057 in accordance with the proposed labeling by patients or health care professionals would literally infringe the asserted claims of the patents-in-suit.

Direct infringement is shown literally when each properly construed claim limitation is literally met by the accused method. *Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1583 (Fed. Cir. 1995) ("Literal infringement exists if each of the limitations of the asserted claim(s) read on, that is, are found in, the accused device.").

2. Infringement Under the Doctrine of Equivalents

For any properly construed claim limitation that Impax argues is not met literally as claimed, the parties may litigate whether the administration or use of the venlafaxine HCl extended-release capsules that are the subject of ANDA No. 78-057 in accordance with the proposed labeling by health care professionals or patients would infringe the asserted claims of the patents-in-suit under the doctrine of equivalents. In light of Impax's Brief Statement of What it Intends to Prove at Trial, it does not appear that Impax is contesting literal infringement under the Court's December 13, 2007 claim construction. D.I. 315 Wyeth submits that the claim construction ruling renders the issue of infringement under the doctrine of equivalents moot.

The test for whether an element of the accused method is equivalent to a claim limitation is whether the differences between the two are insubstantial to one with ordinary skill in the relevant art. *Overhead Door Corp. v. Chamberlain Group, Inc.*, 194 F.3d 1261, 1269 (Fed. Cir. 1999). "[T]he doctrine allows a finding of infringement when the accused product and claimed invention perform substantially the same function in substantially the same way to yield substantially the same result." *Atlas Powder Co. v. E.I. DuPont DeNemours & Co.*, 750 F.2d 1569, 1579 (Fed. Cir. 1984) (citing *Graver Tank*). An important factor to consider in the equivalence analysis is "whether persons reasonably skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 25 (1997).

There are no legal limitations on the doctrine of equivalents that are applicable to the facts of this case. Should Impax assert any legal limitations in its Statement of Issues of Law That Remain to Be Litigated, Wyeth reserves the right to supplement this Statement.

B. Inducing Infringement

The parties will litigate whether Impax's offering to sell, selling, or importing its proposed venlafaxine HCl extended-release capsules that are the subject of ANDA No. 78-057 would actively induce infringement.

In *Allergan, Inc. v. Alcon Labs.*, 324 F.3 1322, 1331-33 (Fed. Cir. 2003), the court stated that where asserted patent claims cover an FDA-approved method of use for which the ANDA applicant is seeking approval, 35 U.S.C. § 271(e)(2) supports an action for induced infringement. Similarly, in *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263, 1272 (Fed. Cir. 2007), the court indicated that Section 271(e)(2) may support an action for induced infringement. Under 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." Direct infringement is a prerequisite to a finding of inducement. *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1378 (Fed. Cir. 2005). Direct evidence of intent is not required; rather, circumstantial evidence may suffice. *Id.* (quoting *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1998)). "Evidence of active steps taken to encourage direct infringement, such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe . . . ." *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005) (internal citations and alterations omitted). Knowledge of the patent is also relevant (though not by itself sufficient) for supporting proof of inducement of infringement. *See MEMC*, 420 F.3d at 1378 n.4 (citations omitted).

Furthermore, one is liable for actively inducing infringement when one knows, or should have known, that one's actions would induce direct infringement. *Fuji Photo Film Co. v. Jazz Photo Corp.*, 394 F.3d 1368, 1377 (Fed. Cir. 2005). *Accord DSU Medical Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006).

C. Contributory Infringement

The parties will litigate whether Impax's offering to sell, selling, or importing its proposed venlafaxine HCl extended-release capsules that are the subject of ANDA No. 78-057 would render Impax liable as a contributory infringer.

Liability for contributory infringement arises when one:

> [O]ffers to sell or sells within the United States or imports into the United States a component of a patented . . . composition, or a material . . . for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use . . . .

35 U.S.C. § 271(c). Contributory infringement, like inducement of infringement, is also appropriate under § 271(e)(2). *Cf. Allergan*, 324 F.3d at 1331 ("[I]n *Glaxo*, we did not limit the scope of section 271(e)(2) to direct infringement actions."). As the Supreme Court pointed out in *Grokster*, infringement under § 271(c) derives from the precept that "'[o]ne who makes and sells articles which are only adapted to be used in a patented combination will be presumed to intend the natural consequences of his acts; he will be presumed to intend that they shall be used in the combination of the patent.'" 544 U.S. at 932 (quoting *New York Scaffolding Co. v. Whitney*, 224 F. 452, 459 (8th Cir. 1915)).

II. VALIDITY

Wyeth's patents are presumed valid. 35 U.S.C. § 282 (2006). Accordingly, to overcome that presumption of validity, Impax bears the burden of proving its invalidity contentions by clear and convincing evidence. *High Concrete Structures, Inc. v. New Enter. Stone & Lime Co.*, 377 F.3d 1379, 1382 (Fed. Cir. 2004).

Furthermore, where, as here, the party challenging the patent is relying on the same references that were before the patent examiner, that party assumes an additional burden:

> When no prior art other than that which was considered by the PTO examiner is relied upon by the attacker, he has the added burden of overcoming the deference that is due to an qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents.

Ultra-Tex Surfaces, Inc. v. Hill Brothers Chemical Co., 204 F.3d 1360, 1367 (Fed. Cir. 2000) (quoting American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed. Cir. 1984).

A. Claim Construction - Preamble Language

Although the Court has already construed the disputed claims (*see* D.I. 315 - 16), Impax seeks to add new claim construction issues in connection with its invalidity defenses through the Pre-Trial Order. Specifically, in its Statement Of Issues Of Law To Be Litigated, Impax asserts that the parties will litigate the issue of whether the preambles of the asserted claims are claim limitations. At the appropriate time, Wyeth will seek permission to move in limine to preclude Impax from asserting that the preambles do not contain limitations. Nevertheless, Wyeth below presents its statement of the law concerning the impropriety of ignoring the claim preambles in this case in the event the Court allows such an argument by Impax.

When considering whether a preamble limits a claim, "the preamble is analyzed to ascertain whether it states a necessary and defining aspect of the invention, or is simply an introduction to the general field of the claim." *On Demand Mach. Corp. v. Ingram Indus.*, Inc., 442 F.3d 1331, 1343 (Fed. Cir. 2006). *See also Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333 (Fed. Cir. 2003) ("[T]he claim preamble sets forth the objective of the method, and the body of the claim directs that the method be performed on someone 'in need' . . . . The preamble

is therefore not merely a statement of effect that may or may not be desired or appreciated. Rather, it is a statement of the intentional purpose for which the method must be performed.").

If the claim drafter uses *both* the preamble and the body of the claim to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects. *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 952 (Fed. Cir. 2006).

If the preamble language represents an "important" or "fundamental characteristic" of the claimed invention, then such language is properly construed as a limitation. *Poly-America, L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1310 (Fed. Cir. 2004) ("Our analysis shows that the inventor considered that the . . . preamble language represented an important characteristic of the claimed invention" and "the preamble language . . . does not state a purpose or an intended use of the invention, but rather discloses a fundamental characteristic of the claimed invention that is properly construed as a limitation of the claim itself.")

B. Anticipation

To show that a patent claim is invalid for anticipation, Impax must prove that a single prior art reference exactly discloses each and every feature of the claimed invention, either expressly or inherently, in a single piece of prior art. *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375-76 (Fed. Cir. 2006).

Although a prior art reference may anticipate without explicitly disclosing a feature of the claimed invention if that missing feature is necessarily present, or inherent, in the single prior art reference, inherency may not be established by probabilities or possibilities. *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981). The mere fact that a certain thing may result from a given set of circumstances is not sufficient. "[A]nticipation by inherent disclosure is appropriate only when the reference discloses prior art that must necessarily include the unstated limitation." *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 1000 (Fed. Cir. 2006); *Accord Oelrich*, 666 F.2d at

581; *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268-69 (Fed. Cir. 1991). Additionally, for a prior art reference to anticipate, it also must describe the invention in a manner that enables one with ordinary skill in the relevant art to understand and make the claimed invention. *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263, 1268 (Fed. Cir. 2007) ("A reference that is not enabling is not anticipating.").

For a printed publication to anticipate an invention claimed in a patent-in-suit, it must be published before the invention by the applicant. 35 U.S.C. § 102(a) (2006). For a printed publication to serve as a statutory time bar, it must be published more than a year before the date of application for the patent-in-suit. 35 U.S.C. § 102(b) (2006). To qualify as prior art under Sections 102(a) or (b), a prior publication published before the invention by the applicant, or more than one year before the date of application for the patent-in-suit, must be reasonably accessible to the public interested in the art. *In re Cronyn*, 890 F.2d 1158, 1160 (Fed. Cir. 1989).

For an invention to have been publicly used by others in this country before the applicant's date of invention, the use must have been publicly accessible. *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998). For an invention to have been publicly used by others in this country more than one year before the application for patent, there must have been a public use of the completed invention. *Allied Colloids Inc. v. American Cyanamid Co.*, 64 F.3d 1570, 1574 (Fed. Cir. 1995). The proper test for public use is whether the use: "(1) was accessible to the public; or (2) was commercially exploited." *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1380 (Fed. Cir. 2005). If the use was experimental, it is not a public use within the meaning of the statute. *T.P. Labs., Inc. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 971 (Fed. Cir. 1984).

For a patent to be invalid based on another's prior invention, the prior invention must have been made in this country by one who did not abandon, suppress, or conceal the invention. 35 U.S.C. § 102(g) (2006).

The first person to reduce the invention to practice is deemed the first inventor, except that the second to reduce the invention to practice will be deemed the first inventor if he or she was the first to conceive the invention and was reasonably diligent in reducing the invention to practice from a time prior to the other inventor's conception. *z4 Techs., Inc. v. Microsoft Corp.*, No. 2006-1638, 2007 U.S. App. LEXIS 26567, at *26 (Fed. Cir. Nov. 16, 2007).

Conception is the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986.) If testing of the invention is required before an alleged inventor can appreciate whether an invention has been made, there is no conception until the invention has been successfully tested. *Invitrogen Corp. v. Clontech Laboratories, Inc.*, 429 F.3d 1052, 1067–69, (Fed. Cir. 2005).

Reduction to practice can be either constructive or actual. *See generally, Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). Actual reduction to practice requires that the claimed invention work for its intended purpose and, "as has long been the law, constructive reduction to practice occurs when a patent application on the claimed invention is filed." *Hybritech, Inc.*, 802 F.2d at 1376.

C. Obviousness

A patent claim is obvious if the differences between the claimed invention and the identified prior art are such that the claimed invention as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the claimed invention pertains. 35 U.S.C. § 103(a) (2006). For a patent to be obvious, a person of ordinary

skill must be shown to have been able to understand the process of combining the prior art references with a reasonable expectation of success. *See Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1378 (Fed. Cir. 2006). The Supreme Court has instructed that "[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant on *ex post* reasoning." *KSR Int'l Co. v. Telefex, Inc.*, 127 S.Ct. at 1727, 1742 (2007).

Patentability is not negatived by the manner in which the invention was made. *Id.* Thus, the path that led the inventors to the invention is not relevant. And because obviousness is determined from the perspective of a person of ordinary skill in the art, and not from the perspective of the actual inventors, the inventor's subjective thoughts, motivations, or expectations are irrelevant. As discussed in *Life Tech., Inc. v. Clontech Lab., Inc.*, 224 F.3d 1320, 1325 (Fed. Cir. 2000) (citations omitted):

> Because patentability is assessed from the perspective of the hypothetical person of ordinary skill in the art, information regarding the subjective motivations of inventors is not material. . . . [T]he path that leads an inventor to the invention is expressly made irrelevant to patentability by statute. *See* 35 U.S.C. § 103(a) ("Patentability shall not be negatived by the manner in which the invention was made."). . . . The only inquiry is whether the teachings of the . . . prior art, would have rendered the claimed invention obvious to one of ordinary skill in the art; this inquiry, as a matter of law, is independent of the motivations that led the inventors to the claimed invention.

Id.

The factors that define the obviousness inquiry are: (1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claims, (3) determining the level of ordinary skill in the pertinent art, and (4) objective indication of non-obviousness (secondary considerations) such as commercial success. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1734 (2007).

The scope and content of the prior art must be considered as a whole. *In re Wesslau*, 353 F.2d 238, 241 (C.C.P.A. 1965) ("It is impermissible . . . to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art."); *see generally In re Kuderna*, 426 F.2d 385, 389 (C.C.P.A. 1970) ("We must approach the issue of patentability in terms of what would have been obvious to one of ordinary skill in the art at the time the invention was made in view of the sum of all the relevant teachings in the art, not in view of first one and then another of the isolated teachings in the art.").

Further, obviousness cannot be predicated on what is unknown, even if the unknown is inherent in a prior art reference. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993).

An invention is not obvious merely because it might have been "obvious to try." When obviousness is asserted based on an obvious-to-try basis, there must be a "finite number of identified, *predictable* solutions" and the success ultimately derived from pursuing those solutions must have been "*anticipated success*." *KSR Int'l Co.*, 127 S.Ct. at 1742 (emphasis added). Thus, *KSR* does not overrule or supplant Federal Circuit precedent requiring a reasonable expectation of success.

The Supreme Court has instructed that courts also must evaluate "secondary considerations" of obviousness, i.e., other objective factors that may show that an invention was not obvious from the prior art. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

Evidence rebutting obviousness may include: evidence of unexpected results, evidence that the prior art teaches away from the claimed invention in any material respect, and evidence of secondary considerations such as commercial success, copying, skepticism, and long-felt but

unresolved need. *In re Sullivan*, 498 F.3d 1345, 1351 (Fed. Cir. 2007); *Advanced Display Systems, Inc. v. Kent State Univ.*, 212 F.3d 1272, 1285 (Fed. Cir. 2000); *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 885 (Fed. Cir. 1998).

Unexpected results, in the eyes of one of ordinary skill in the art, rebut a *prima facie* case of obviousness. *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995). Given the presumption of similar properties for similar compositions, substantially improved properties are *ipso facto* unexpected. *Id.* at 751.

Unexpected results cannot be ignored. *Sullivan*, 498 F.3d at 1353 ("claimed composition exhibits the unexpected property of neutralizing the lethality of rattlesnake venom while reducing the occurrence of adverse immune reactions in humans. Such a use and unexpected property cannot be ignored."); *see also Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1362 (Fed. Cir. 2007).

Unexpected results need not be recited in the claims. *In re Merchant,* 575 F.2d 865, 869 (C.C.P.A. 1978) ("We are aware of no law requiring that unexpected results relied upon for patentability be recited in the claims.").

Subject matter developed by another person, which qualifies as prior art only under subsections (e), (f), and (g) of section 102, shall not preclude patentability under section 103 where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. 35 U.S.C § 103(c)(1) (2006).

Impax asserts that evidence of commercial success has no force when there is a patent barring the practice of the invention, relying on *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). Impax reads *Merck* too broadly. In *Merck*, the Federal Circuit

recognized that "commercial success may have probative value for finding non-obviousness of Merck's weekly dosing regimen in some context . . . ." *Id.* at 1337. For an example of such a context, see *Syntex LLC v. Apotex, Inc.*, where the Court found that commercial success derived from the entire combination taught by the patent-in-suit, and not from the fact that its active ingredient was previously protected by another patent. *Syntex LLC v. Apotex, Inc.*, No. C 01-02214 MJJ, 2006 U.S. Dist. LEXIS 36089, at *74-75 (N.D. Cal. June 2, 2006) ("This conclusion is apparent from the facts that, in terms of sales and market share, . . . ACULAR(R) has consistently outperformed ACULAR PF(R), a formulation of ACULAR(R) that contains the same active ingredient as ACULAR(R) . . . ."), *aff'd*, 221 Fed. Appx. 1002 (Fed. Cir. 2007).

D. Written Description

For a claim to be invalid for lack of written description, the specification must fail to convey to one skilled in the relevant art that the inventors were in possession, at the time the specification was filed, of what is in the claim. *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1320 (Fed. Cir. 2003).

Original claims are also considered for purposes of determining compliance with the written description requirement. *In re Koller*, 613 F.2d 819, 823 (C.C.P.A. 1980); *In re Gardner*, 475 F.2d 1389, 1391 (C.C.P.A. 1973) ("Claim 2, which apparently was an original claim, in itself constituted a description in the original disclosure equivalent in scope and identical in language to the total subject matter now being claimed. . . . Nothing more is necessary for compliance with the description requirement . . . ."). *See also Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 998, n.4 (Fed. Cir. 2000) ("One of this court's predecessor court's clarified that disclosure in an originally filed claim satisfies the written description requirement.").

E. Enablement

A patent applicant must provide a written description of the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...." 35 U.S.C. § 112, ¶ 1 (2006). For a patent to be invalid for lack of enablement, the specification must fail to "teach those in the art to make and use the invention without undue experimentation." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Accordingly, to establish that a patent is invalid for lack of an enabling disclosure, the challenger must prove by clear and convincing evidence that a person skilled in the relevant art, using the knowledge available to such a person and the disclosure in the patent document, could not make and use the invention without undue experimentation. *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941 (Fed. Cir. 1990).

"The key word is 'undue,' not 'experimentation'" because "[e]nablement is not precluded by the necessity for some experimentation such as routine screening." *In re Wands*, 858 F.2d at 736-37. *Accord Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986). Factors to be considered in determining whether a disclosure would require undue experimentation include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 858 F.2d at 737.

Lastly, "[t]he enablement requirement is met if the description enables any mode of making and using the claimed invention." *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991); *accord John Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed.

Cir. 1998); *see also Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1335 (Fed. Cir. 2003); *Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1307-08 (Fed. Cir. 2001).

F. Inventorship

It is presumed that a patent's named inventors are the true and only inventors. *Cook Biotech, Inc. v. Acell, Inc.*, 460 F.3d 1365, 1381 (Fed. Cir. 2006). Thus, for a patent to be invalid for non-joinder of an alleged co-inventor, Impax must prove by clear and convincing evidence that somebody other than the named inventors contributed to the conception of the invention claimed in the patent.

An alleged co-inventor "must show that he made 'a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and [did] more than merely explain to the real inventors well-known concepts and/or the current state of the art.'" *Acromed Corp. v. Sofamor Danek Group, Inc.*, 253 F.3d 1371, 1379 (Fed. Cir. 2001), quoting *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998).

An inventor "may use the services, ideas, and aid of others in the process of perfecting his invention without losing his right to a patent." *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 624 (Fed. Cir. 1985). This has long been the law. *See generally, O'Reilly v. Morse*, 56 U.S. 62, 111 (1853), where the Supreme Court, in holding that Samuel Morse's discussions with scientists in connection with his invention of the telegraph did not alter his status as the sole inventor of that device, stated:

> No invention can possibly be made, consisting of a combination of different elements . . . without a thorough knowledge of the properties of each of them, and the mode in which they operate on each other. And it can make no difference, in this respect, whether [the inventor] derives his information from books, or from conversation with men skilled in the science. If it were otherwise,

> no patent, in which a combination of different elements is used, could ever be obtained.

For example, one who does "no more than a skilled salesman would do in explaining how his employer's product could be used to meet a customer's requirements" is not a co-inventor. *Hess v. Advanced Cardiovascular Sys.*, 106 F.3d 976, 981 (Fed. Cir. 1997) (alleged co-inventor "was 'doing nothing more than explaining to the inventors what the then state of the art was and supplying a product to them for use in their invention'; that 'most, if not all, of his discussion with them were [sic] telling them what was available in the marketplace by way of product, and telling them how the product worked', and that 'what Mr. Hess was doing was showing them available product, telling them its properties, telling them how it could be used, and how it might be used.'"). *See also, Caterpillar Inc. v. Sturman Industries*, 387 F.3d 1358, 1378 (Fed. Cir. 2004) (individuals who identified 52100 and 4140 as grades of steel to use for residual magnetic latching in claimed invention did not make a significant enough contribution to qualify as inventors where "various publicly available texts and patents describe the basic magnetic properties of 52100 and 4140 steel.")

G. Indefiniteness

Wyeth contends that, given the Court's claim construction ruling, Impax should be precluded from asserting that the claim term "therapeutic metabolism" is indefinite. Should the court decide to entertain that issue, Wyeth provides the following brief statement of law.

In the December 13, 2007 claim construction ruling the Court construed the claim term "eliminating the troughs and peaks of drug concentration in a patient's blood plasma . . . attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride." The Court determined that the phrase was amenable to construction and construed it as follows:

> A method in which the extended-release formulation is administered once in a 24-hour period, resulting in a venlafaxine

> blood plasma concentration that rises to a maximum value, followed by a generally protracted decrease over the remaining period while maintaining during that 24-hour period levels of venlafaxine in blood plasma that are sufficient to provide, during the course of treatment, relief from the condition being treated, thereby eliminating the multiple sharp peaks and troughs resulting from multiple daily dosing of the same total daily dose of the immediate release formulation as reflected in a graph of venlafaxine blood plasma concentration versus time.

D.I. 315 at 17-18. Because the Court was able to discern the meaning of this claim language, which includes "therapeutic metabolism," the claim is not indefinite as a matter of law. Exxon Research & Engineering Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001) ("If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds.").

III. ENFORCEABILITY

Impax bears the burden of proving its inequitable conduct allegations by clear and convincing evidence. *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988).

Inequitable conduct occurs when a patent applicant breaches his or her duty to the United States Patent and Trademark Office (PTO) of candor, good faith, and honesty. *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1381 (Fed. Cir. 2006). Such a breach occurs if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1380 (Fed. Cir. 2006).

The doctrine of inequitable conduct requires a trial court to undertake a two-step analysis. *Halliburton Co. v. Schlumberger Technology Corp.*, 925 F.2d 1435, 1439 (Fed. Cir. 1991). The trial court must discern whether the withheld references satisfy a threshold level of materiality.

Id. The court must also determine whether the applicant's conduct satisfies a threshold showing of intent to mislead. *Id.* The party asserting inequitable conduct must prove a threshold level of materiality and intent by clear and convincing evidence. *Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006). To determine whether the applicant's conduct was intentional, "the involved conduct, viewed in light of all the evidence, including evidence of good faith, must indicate sufficient culpability to require a finding of intent to deceive." *Id.* at 1319.

One measure of materiality is set forth in current PTO Rule 56. *Id.* at 1314-16. This version of the rule, which was in place during the prosecution of the patents-in-suit, states: "Information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability." 37 C.F.R. § 1.56(b). An earlier version of Rule 56 provided that materiality requires a showing that a reasonable examiner would have considered the withheld information important in deciding whether to allow the patent. *Digital Control*, 437 F.3d at 1314. The Federal Circuit has concluded that the current Rule 56 standard and the former "reasonable examiner" standard are essentially the same. *Id.* at 1316.

To the extent that one materiality standard requires a higher showing of materiality than another standard, the requisite finding of intent may be lower. *Id.* Impax's assertion that a sliding scale is used to evaluate the sufficiency of the evidence is wrong. Before the Court balances the factors, there must be clear and convincing evidence of both a threshold levels of

materiality and a threshold level of intent. *Eli Lilly & Co.*, 471 F.3d at 1381. Only after finding a threshold level of materiality and a threshold level of intent does the court balance those factors. *Id.*

An applicant has no obligation to disclose an otherwise material reference if it is cumulative or less material than the references already before the examiner. *Halliburton*, 925 F.2d at 1440. When weighing whether uncited prior art is more material than the art before the examiner, a trial court considers the similarities and differences between prior art and the claims of the patent. *Id.* at 1441. In making this determination, the trial court must consider portions of prior art references that teach away from the claimed invention. *Id.*

Impax's assertion that intent to deceive is "normally" inferred from the facts and circumstances surrounding a knowing failure to disclose material information is not correct. In a case involving an omission of an alleged material reference to the PTO, the record must contain clear and convincing evidence that the applicant made a deliberate decision to withhold a known material reference, and the applicant must have withheld the material subject matter with the intent to deceive. *Eli Lilly & Co.*, 471 F.3d at 1382. Intent to deceive cannot be inferred simply from the decision to withhold the reference where the reasons given for the withholding are plausible. *Id.*

Inequitable conduct requires an intent to act inequitably. *Halliburton*, 925 F.2d at 1442. Materiality of an undisclosed reference does not presume an intent to deceive. *Id.* Further, a mere showing that references having some degree of materiality were not disclosed does not establish inequitable conduct. *Id.*

Gross negligence does not in and of itself justify an inference of intent to deceive. *Kingsdown Medical Consultants*, 863 F.2d at 876. Negligent conduct can support an inference

of intent only where, viewed in light of all the evidence, including evidence indicative of good faith, the conduct is culpable enough to require a finding of intent to deceive. *Id.* Thus, contrary to Impax's assertion, failing to learn of a reference's materiality because of "gross negligence" is not a basis for establishing inequitable conduct.

An error in determining inventorship does not in and of itself constitute inequitable conduct. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1576 (Fed. Cir. 1996). Nor can there be inequitable conduct where the allegedly omitted co-inventor makes no claim of inventorship. *Id.* ("When an alleged omitted co-inventor does not claim to be such, it can hardly be inequitable conduct not to identify that person to the PTO as an inventor.").

Finally, "[e]ven when a court finds that the patentee failed to disclose material information to the PTO and acted with deceptive intent, the court retains discretion to decide whether the patentee's conduct is sufficiently culpable to render the patent unenforceable." *Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. de C.V.*, 464 F.3d 1339, 1346 (Fed. Cir. 2006).

IV. RELIEF

Whether Wyeth is entitled, under 35 U.S.C. § 271(e)(4)(A), to an Order that the effective date of any FDA approval of Impax's proposed venlafaxine HC1 extended-release capsules that are subject of ANDA No. 78-057 shall be a date which is not earlier than (1) the expiration date of U.S. Patent No. 6,274,171 B1; (2) the expiration date of U.S. Patent No. 6,403,120 B1; (3) the expiration date of U.S. Patent No. 6,419,958 B2; and (4) any later date of exclusivity to which Wyeth is or becomes entitled?

Whether Wyeth is entitled, under 35 U.S.C. § 271(e)(4)(B), to a permanent injunction, restraining and enjoining Impax from engaging in the commercial manufacture, use, offer for sale, or sale of its proposed venlafaxine HC1 extended-release capsules within the United States,

or importation into the United States until the expiration of the patents-in-suit or any later date of exclusivity to which Wyeth is or becomes entitled? *See Abbott Labs. v. Torpharm, Inc.*, 503 F.3d 1372 (Fed. Cir. 2007)(recognizing that district court has full authority to issue a permanent injunction prohibiting an ANDA applicant from "commercially manufacturing, using, selling, or offering for sale" in the United States a proposed generic product found to be infringing the plaintiff's patent.)

V. ATTORNEYS' FEES

Whether this case is exceptional such that Wyeth is entitled to its attorneys' fees?

EXHIBIT E

IMPAX'S STATEMENT OF ISSUES OF LAW TO BE LITIGATED

The following legal issues remain to be litigated.[1] To the extent that any of the issues of fact set forth in Impax's Statement of Issues of Fact That Remain to Be Litigated are properly considered issues of law, Impax incorporates those portions of that Statement herein by reference. To the extent any of the issues set forth in this Statement of Issues of Law That Remain to Be Litigated are properly considered issues of fact, Impax incorporates those portions of this Statement into its Statement of Issues of Fact That Remain to Be Litigated.

A. Impax would not infringe the patents-in-suit under the Impax construction of the claim term "extended release formulation."

1. Had this Court adopted Impax's proposed construction of the claim term "extended release formulation," the parties would have litigated whether Impax's accused extended-release venlafaxine product, if marketed and sold within the United States, would directly infringe any of the asserted claims of the patents-in-suit, either literally or under the doctrine of equivalents, or would indirectly infringe any of the asserted claims of the patents-in-suit, either by contributing to infringement of the claims in the United States or by knowingly inducing others to infringe the claims in the United States.

2. An infringement analysis consists of two steps. First, the Court determines the meaning and scope of the asserted patent claims. *See Aquatex Indus., Inc. v. Techniche Solutions,* 419 F.3d 1374, 1380 (Fed. Cir. 2005). Second, the properly construed claims are compared to the accused product or process. *See id.* Claims may be limited to process steps disclosed in the patent specification if such steps are an essential part of the claimed invention. *See Anderson Corp. v. Fiber Composites, LLC,* No. 05-1434, 06-1009, slip op. at 23 (Fed. Cir.

[1] In light of the Court's recent claim-construction ruling, and in order to create a record in case of appeal, Impax also intends to make an offer of proof regarding the evidence it would have presented regarding non-infringement and invalidity had the Court accepted Impax's proffered constructions of the disputed claim terms in the asserted claims of the patents-in-suit. In the interest of completeness, this list contains issues of law on which Impax intends to make such offers of proof.

Jan. 26, 2007).

3. A claim term can be given its correct construction only within the context of "what the inventors actually invented and intended to envelop with the claim." *Phillips v. AWH Corp.*, 415 F.3d at 1303, 1316 (Fed. Cir. 2005). A claim term should be construed to mean "what one of ordinary skill in the art at the time of the invention would have understood the term to mean." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 986 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). But "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313. "In general, the scope and outer boundary of claims is set by the patentee's description of his invention." *On Demand Mach. Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1338 (Fed. Cir. 2006). The specification is usually "dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Moreover, a patentee is free to serve as his own lexicographer: "if the patent inventor clearly supplies a different meaning [from the ordinary meaning], the claim should be interpreted accordingly." *Adobe Sys. Inc. v. Macromedia, Inc.*, 201 F. Supp. 2d 309, 314 (D. Del. 2002) (citing *Markman*, 52 F.3d at 980).

4. The preamble of a patent claim consists of the words at the beginning of the claim that precede the transitional phrase (such as "comprising" or "which comprises"). *See generally, e.g., Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336 (Fed. Cir. 2002). "Preambles are used primarily to give the field within which the invention has utility." 1 DELLER, PATENT CLAIMS § 163 (2d ed. 1971).

5. The Federal Circuit recognizes two circumstances in which preambles limit claim scope. First, "a preamble limits the invention if it recites essential general structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). For example, when the meaning of

a term in the claim body depends on a phrase used in the preamble, the preamble may limit the claim scope "because it indicates a reliance on both the preamble and claim body to define the claimed invention." *Catalina,* 289 F.3d at 808. "Likewise, when the preamble is essential to understand limitations of terms in the claim body, the preamble limits claim scope." *Id.* Second, where a patentee successfully distinguished over prior art by relying on the preamble, that "transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." *Id.* But "[w]ithout such reliance ... a preamble generally is not limiting when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention." *Id.* at 809. In other words, "preamble language merely extolling benefits or features of the claimed invention does not limit the claim scope without clear reliance on those benefits or features as patentably significant." *Id.; see also STX, LLC v. Brine, Inc.,* 211 F.3d 588, 591 (Fed. Cir. 2000) (preamble stating that invention provides "improved playing and handling characteristics" is not a limitation); *Bristol-Myers Squibb Co. v. Ben Venue Labs, Inc.,* 246 F.3d 1368, 1375 (Fed. Cir. 2001) (steps of claimed method performed in the same way regardless whether intended results described in preamble ultimately occur).

1. Impax would not literally infringe the patents-in-suit.

6. Literal infringement can be found only if "every limitation recited in the claim appears in the accused device, i.e., when 'the properly construed claim reads on the accused device exactly.'" *DeMarini Sports, Inc. v. Worth, Inc.,* 239 F.3d 1314, 1331 (Fed. Cir. 2001).

7. A method or process consists of one or more operative steps, and, accordingly, "[i]t is well established that a patent for a method or process is not infringed unless all steps or stages of the claimed process are utilized." *NTP, Inc. v. Research in Motion, Ltd.,* 418 F.3d 1282, 1318 (Fed. Cir. 2005).

2. Impax would not infringe the patents-in-suit under the doctrine of equivalents.

8. If there is no literal infringement, the doctrine of equivalents may be considered only to the extent it is not precluded by the doctrine of prosecution-history estoppel. *See*

Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 40 (1997). Further, where an accused infringer is merely practicing the prior art, it has a "complete defense" to an infringement claim. *See Sextant Avionique, S.A. v. Analog Devices, Inc.*, 172 F.3d 817, 827 (Fed. Cir. 1999).

9. The prosecution history of a patent-in-suit limits the application of the doctrine of equivalents in at least two important ways. First, when a patentee describes subject matter in the patent specification, but does not claim that subject matter in the patent claims, the patentee may not use the doctrine of equivalents to "recapture subject matter deliberately left unclaimed." *Johnson & Johnston Assocs. v. R.E. Service Co.*, 285 F.3d 1046, 1059-60 (Fed. Cir. 2002). Instead, that unclaimed subject matter is dedicated to the public. A teaching is dedicated to the public "if one of ordinary skill in the art can understand the unclaimed disclosed teaching upon reading the written description." *PSC Computer Prods., Inc. v. Foxconn Int'l.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004).

10. Second, when "the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection [by a patent examiner], he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent." *Festo Corp. v. Shokestsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733-34 (2002). Where the patentee acquiesces in the examiner's limitation of the scope of the claims in order to avoid prior art, the patentee's "decision to forego an appeal and submit an amended claim is taken as a concession that the invention as patented does not reach as far as the original claim," and the surrendered claim scope may not be recaptured by recourse to the doctrine of equivalents. *Id.* at 734. Such a narrowing may be made in the patent specification, statement or arguments made to the examiner, or amendments made during prosecution. *See id.* at 740-41; *see also Astrazeneca AB, Aktiebolaget Hassle, KBI-E, Inc. v. Mutual Pharm. Co., Inc.*, 384 F.3d 1333, 1341-42 (Fed. Cir. 2004).

11. Amendment-based estoppel bars the application of the doctrine of equivalents.

"When a patentee makes a narrowing amendment to a claim, the patent holder has the burden to demonstrate that the reason for the amendment was unrelated to patentability (e.g., to avoid prior art)." *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1363 (Fed. Cir. 2006). "When the record lacks explanation for an amendment," there is a presumption "that the PTO had a substantial reason related to patentability for including the limiting element added by amendment." *Id.* This requires reviewing courts to "presume that the patentee surrendered all subject matter between the broader and narrower language." *Id.* (citing *Festo*, 535 U.S. at 739). This presumption cannot be rebutted unless the patentee shows "that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." *Id.*

12. Argument-based estoppel also bars the application of the doctrine of equivalents when the prosecution history demonstrates the applicant's "clear and unmistakable surrender of subject matter." *Conoco*, 460 F.3d at 1364. "The relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *Id.*

13. If none of these limitations bar the application of the doctrine of equivalents, "[a]n element in the accused product is equivalent to a claim limitation if the differences between the two are 'insubstantial' to one of ordinary skill in the art." *Eagle Comtronics Inc. v. Arrow Comm'n Labs., Inc.*, 305 F.3d 1303, 1315 (Fed. Cir. 2002). It is relevant whether the alleged equivalent element in the accused device "performs substantially the same function in substantially the same way to achieve the same result" as that of the missing element of the claimed invention. *Id.* (citing *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950)). But "equivalency [must] be proven with 'particularized testimony and linking arguments.'" *Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1566-67 (Fed. Cir. 1996). This ensures that the fact finder has an "analytical framework for making its decision," and that the reviewing court is assured that the trier of fact "was fully presented with a basis for applying the doctrine of equivalents." *Id.* at 1567.

14. By contrast, when an accused infringer's product or process is "so far changed in

principle from a patented article that it performs the same or similar function in a substantially different way," the accused product or process does not infringe. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1351 (Fed. Cir. 2003). This "reverse doctrine of equivalents" is used to "restrict the claim and defeat the patentee's action for infringement," even where the accused infringer's product or process falls within the literal words of the claim. *Tate Access Floors, Inc. v. Interface Architectural Resources, Inc.*, 279 F.3d 1357, 1368 (Fed. Cir. 2002).

3. Impax would not contribute to infringement of the Wyeth patents in the United States.

15. Contributory infringement cannot occur in the absence of direct infringement. *See Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 773 (Fed. Cir. 1993). But to give rise to liability for contributory infringement, the predicate direct infringement must occur in the United States. 35 U.S.C. § 271(a); *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1374 (Fed. Cir. 1991).

16. To prove contributory infringement, the patentee must prove that the accused infringer (1) sold or offered to sell within the United States; (2) a material component of a patented article or a material component used in practicing a patented process; (3) which item is not a staple article of commerce suitable for substantial non-infringing use; (4) with knowledge that the item sold, offered, or imported is especially made or adapted for use in an infringement of a patent; and (5) that such direct infringement did occur. 35 U.S.C. § 271(c).

17. A patentee must prove that the accused contributory infringer's components have no substantial non-infringing uses in order to prove contributory infringement. *See Golden Blount, Inc. v. Robert H. Peterson Co.*, 365 F.3d 1054, 1060 (Fed. Cir. 2004).

4. Impax would not induce infringement of the Wyeth patents in the United States.

18. Inducement of infringement cannot occur in the absence of direct infringement. *See DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1302 (Fed. Cir. 2006). But to give rise to liability for inducement, the predicate direct infringement must occur in the United States. 35 U.S.C. § 271(a); *Joy Techs.*, 6 F.3d at 774.

19. The plaintiff has the burden of showing that the alleged inducer's actions induced direct infringing acts within the United States and that the alleged inducer knew that its actions would induce direct infringement. *DSU*, 471 F.3d at 1302. This means that the patent holder must prove that, once the accused inducer knew of the patent, it actively and knowingly aided and abetted another's direct infringement. *Id.* at 1305. Inducement thus requires evidence of culpable conduct directed to encouraging another's direct infringement, not merely that the inducer had knowledge of the direct infringer's activities. *Id.* at 1306.

B. All asserted claims of the patents-in-suit are invalid.

20. The parties will litigate whether any of the asserted claims of the patents-in-suit are invalid. Impax has the burden of establishing invalidity by clear and convincing evidence. *See Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1320 (Fed. Cir. 2004).

1. Invalidity and the prior art.

21. The parties may litigate the scope and content of the relevant prior art to Wyeth's patents. An issued patent may be invalid over prior art in certain circumstances. Specifically, a patent claim will be invalid if "the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent." 35 U.S.C. § 102(a). Further, a patent claim will be invalid if "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b).

22. Under section 102(a), the knowledge of use will be prior art if it was: (1) a public use; (2) by someone other than the inventor; (3) before the inventor's date of invention; and (4) in the United States. *See Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998). Under section 102(b), any prior public use or secret commercial use that occurred more than one year before the patent was filed qualifies as prior art. A prior publication, published before the established invention date or one year prior to the filing date, qualifies as prior art under section 102(a) or (b), respectively, if it was reasonably accessible to the portion of

the public most likely to use it. *See In re Cronyn*, 890 F.2d 1158, 1160 (Fed. Cir. 1989).

23. A prior patent that issued anywhere in the world before the invention of the patent in suit or more than one year before the application leading to the patent in suit qualifies as prior art. 35 U.S.C. § 102(a), (b); *Lamb-Weston, Inc. v. McCain Foods, Ltd.*, 78 F.3d 540, 545 (Fed. Cir. 1996).

24. "The key inquiry is whether or not a reference has been made 'publicly accessible.'" *In re Klopfenstein*, 380 F.3d 1345, 1348-50 (Fed. Cir. 2004). This is the criterion by which a prior art reference is judged for purposes of section 102(b). *See id.* The test for determining whether a reference was publicly accessible is whether "it has been disseminated or otherwise made available to the extent that persons interested and of ordinary skill in the subject matter or art [ ] exercising reasonable diligence can locate it." *Massachusetts Inst. of Tech. v. AB Fortia*, 774 F.2d 1104, 1109 (Fed. Cir. 1985).

25. A patent claim is invalid under 35 U.S.C. § 102(g) "if a patentee's invention has been made by another, prior inventor who has not abandoned, suppressed, or concealed the invention." *Dow Chemical Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1339 (Fed. Cir. 2001). Generally, an invention was not abandoned, suppressed, or concealed if it was made public, sold or offered for sale, or otherwise used for a commercial purpose. *See id.* at 1342-43.

26. Reduction to practice under section 102(g)(2) can be actual or constructive. *See In re Katz*, 687 F.2d 450, 454 (C.C.P.A. 1982); *Roberts v. Sears, Roebuck & Co.*, 665 F. Supp. 671 (N.D. Ill. 1987) (rejecting plaintiff's argument that constructive reduction to practice is not enough under section 102(g), "given the numerous cases in which constructive reduction was applied where patentability was at issue").

2. The preambles of the asserted claims do not limit claim scope.

27. The parties will litigate the issue whether the preambles of the asserted claims of the patents-in-suit limit the scope of those claims. The preamble of a patent claim consists of the words at the beginning of the claim that precede the transitional phrase (such as "comprising" or "which comprises"). *See generally, e.g., Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336

(Fed. Cir. 2002). "Preambles are used primarily to give the field within which the invention has utility." 1 DELLER, PATENT CLAIMS § 163 (2d ed. 1971).

28. The Federal Circuit recognizes two circumstances in which preambles limit claim scope. First, "a preamble limits the invention if it recites essential general structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). For example, when the meaning of a term in the claim body depends on a phrase used in the preamble, the preamble may limit the claim scope "because it indicates a reliance on both the preamble and claim body to define the claimed invention." *Catalina*, 289 F.3d at 808. "Likewise, when the preamble is essential to understand limitations of terms in the claim body, the preamble limits claim scope." *Id.*

29. Second, where a patentee successfully distinguished over prior art by relying on the preamble, that "transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." *Id.* But "[w]ithout such reliance ... a preamble generally is not limiting when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention." *Id.* at 809. In other words, "preamble language merely extolling benefits or features of the claimed invention does not limit the claim scope without clear reliance on those benefits or features as patentably significant." *Id.; see also STX, LLC v. Brine, Inc.*, 211 F.3d 588, 591 (Fed. Cir. 2000) (preamble stating that invention provides "improved playing and handling characteristics" is not a limitation); *Bristol-Myers Squibb Co. v. Ben Venue Labs, Inc.*, 246 F.3d 1368, 1375 (Fed. Cir. 2001) (steps of claimed method performed in the same way regardless whether intended results described in preamble ultimately occur).

3. The '958 patent is invalid because it is anticipated.

30. The parties will litigate whether the '958 patent is anticipated and/or obvious in view of the prior art. Anticipation is found where a single reference, either expressly or inherently, discloses every limitation of the claimed invention. *See Novo Nordisk Pharms., Inc.*

v. Bio Technology General Corp., 424 F.3d 1347, 1354 (Fed. Cir. 2005); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349-50 (Fed. Cir. 2002).

31. "It is well established that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it. Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." *Cruciferous Sprout*, 301 F.3d at 1349.

32. A reference need not enable its own invention to anticipate a later invention. Instead, "[t]o serve as an anticipating reference, the reference must enable that which it is asserted to anticipate." *Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003). It is not necessary that an invention disclosed in a publication have actually been made in order to satisfy the enablement requirement. *Id.* at 1055. Anticipation requires only that the prior art disclosure of the claimed invention be enabling to one of ordinary skill in the art. *See id.*

4. The asserted claims of the patents-in-suit are invalid because they are obvious.

33. The parties will litigate whether the patents-in-suit are invalid because they are obvious. A patent claim is invalid under 35 U.S.C. § 103(a), even if it is not identically disclosed by a single piece of prior art, if the differences between the subject matter claimed and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to an person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. § 103(a). Obviousness is a question of law. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1333 (Fed. Cir. 2005). Whether a patent claim is obvious turns on the factors set out in *Graham v. John Deere Co.*, 383 U.S. 1 (1966): (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed subject matter and the prior art; and (4) secondary considerations suggesting non-obviousness. *See id.* at 17-18.

34. Earlier this year, in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007), the United States Supreme Court emphasized that the obviousness inquiry is pragmatic and flexible: "The obviousness analysis cannot be confined by a formalistic conception of the words

teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents." *KSR*, 127 S.Ct. at 1741. Instead, the Supreme Court urged a "common sense" approach to the use of customary knowledge in the obviousness equation: "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id.* at 1742. Accordingly, the Supreme Court recognized that an "invention" is obvious where it consists of a combination of prior art that would have been obvious to try to a person of ordinary skill in the art:

> Where there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

Id. Since *KSR*, subsequent Federal Circuit cases have employed this common sense approach to determining obviousness. *See Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007); *Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007); *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007); *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157 (Fed. Cir. 2007); *In re Icon Health & Fitness, Inc.*, 2007 WL 2189161 (Fed. Cir. Aug. 1, 2007).

35. On October 10, 2007, the U.S. Patent and Trademark Office issued Guidelines "to assist Office personnel to make a proper determination of obviousness under section 103, and to provide a supporting rationale in view of" *KSR*. *See* United States Patent and Trademark Office, *Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in* KSR International Co. v. Teleflex Inc., 72 Fed. Reg. 57526 (Oct. 10, 2007). In the Guidelines, the PTO articulates seven separate bases for a finding of obviousness, *id.* at 57529, including:

- "Combining prior art elements according to known methods to yield predictable results."

- "Use of known techniques to improve similar devices (methods, or products) in the same way."
- "Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results."
- "'Obvious to try'—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success. To reject a claim as "obvious to try," the PTO Guidelines tell examiners to articulate: "(1) a finding that at the time of the invention, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem; (2) a finding that there had been a finite number of identified, predictable potential solutions to the recognized need or problem; (3) a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success; and (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness." *Id.* at 57532.
- "Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention."

36. The first step in any obviousness analysis is to determine the scope and content of the prior art. Under section 103, a reference need not be enabled to qualify as prior art. *See Amgen,* 314 F.3d at 1357.

37. As noted above, "[i]t is well established that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." *Cruciferous Sprout,* 301 F.3d at 1349. Further, "the fact that a characteristic is a necessary feature of a prior art embodiment (that is itself sufficiently described and enabled} is enough for

inherent anticipation, even if that fact was unknown at the time of the prior invention." *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1321 (Fed. Cir. 2004). Similarly, where a prior art reference, or a combination of such references, inherently embodies a particular benefit, that benefit is inherently obvious over the prior art. *See In re Dillon*, 919 F.2d 688, 694 (Fed. Cir. 1990) (en banc).

38. A reference disclosing more than one alternative constitutes a teaching away from the patented system where the disclosure criticizes, discredits, or otherwise discourages the solution claimed. *See In re Fulton*, 391 F.3d 1195, 1200-01 (Fed. Cir. 2004).

39. The secondary considerations suggesting non-obviousness may include commercial success, failure of others, licenses, unexpected results, and simultaneous development by others. *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1129 (Fed. Cir. 2000). There must be a nexus between the secondary consideration and the claimed invention for the secondary consideration to be relevant to the obviousness inquiry. *Id.* at 1130.

40. "Commercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art." *Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). This "chain of inferences," leads from the commercial success of the patented product to the inference that "attempts [by other would-be innovators] have been made and have failed." *Id.* at 1376-77 (internal quotation omitted). But the commercial success of a product embodying a patented invention, and cannot rebut a finding of obviousness, where some other factor, such as a separate patent, barred others from practicing the invention. *Id.* at 1376-77. For example, in *Merck*, the Federal Circuit found the commercial success of a brand-name drug product "has no force " because other would-be market entrants "were legally barred from commercially testing" competing products by an unasserted patent on the administration of the drug. *Id.*

41. Just as the failure of others to make the invention may be evidence that an

invention would not have been obvious, independent making of the invention by persons other than the inventor at about the same time may be evidence that the invention would have been obvious. *Ecolochem, Inc. v. Southern Cal. Edison Co.*, 227 F.3d 1361, 1379 (Fed. Cir. 2000).

5. The patents-in-suit are invalid for lack of adequate written description.

42. The parties will litigate whether the patents-in-suit are invalid for lack of adequate written description. Section 112 requires that "[t]he specification shall contain a written description of the invention." 35 U.S.C. § 112. This written-description requirement is distinct from the enablement requirement also found in section 112. *See Invitrogen*, 429 F.3d at 1071. The written-description requirement mandates that, for a patent to be valid, the patent's specification "must describe the invention sufficiently to convey to a person of skill in the art that the patentee had possession of the claimed invention at the time of the application." *Lizardtech*, 424 F.3d at 1344-45. The specification must further describe the invention "with all its claimed limitations, . . . and by using 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.'" *Regents of the Univ. of Calif. v. Eli Lilly and Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997) (citation omitted); *see also Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998) (quoting *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)). Accordingly, "a broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope." *Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317, 1323 (Fed. Cir. 2002).

43. Accordingly, to satisfy the written-description requirement, the specification must describe the full scope of the claimed invention. *See Lizardtech*, 424 F.3d at 1344-45.

44. In *ICU Medical, Inc. v. Alaris Medical Sys., Inc.*, 2007 U.S. Dist. Lexis 13156, *36-40 (C.D. Cal. Jan 22, 2007), one district court recently applied these principles in evaluating a patent similar to the patents-in-suit. There, the patent included claims to both "spike" and "spikeless" embodiments of a needleless medical valve. *Id.* at *4. But the specification of the patent included no written description of any "spikeless" embodiment, and thus was found

invalid for insufficient written description. *Id.* at *35-40.

6. The patents-in-suit are invalid for lack of enablement.

45. The parties will litigate whether the patents-in-suit are invalid for lack of enablement. A patent's specification must "contain a written description ... of the manner and process of making and using [the invention] ... in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most closely connected, to make and use the same." 35 U.S.C. § 112 (2000). Accordingly, patent law requires that "the patent specification enable those skilled in the art to make and use the full scope of the claimed invention without undue experimentation." *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1070 (Fed. Cir. 2005). A patent is invalid if it is not enabled. *See Festo,* 535 U.S. 722, 736 (2002).

46. Whether undue experimentation is required, therefore rendering a patent invalid for lack of enablement, depends upon a factual inquiry, including consideration of (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented in the patent specification; (3) the presence of absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. *See Falkner v. Inglis,* 448 F.3d 1357, 1366 (Fed. Cir. 2006). This inquiry can invalidate "patent claims as not having been enabled, despite the PTO's having allowed those claims." *AK Steel Corp. v. Sollac,* 344 F.3d 1234, 1245 (Fed. Cir. 2003).

47. "[A]n inventor's failed attempts to practice an invention are relevant evidence of non-enablement." *Novo Nordisk,* 424 F.3d 1347, 1362 (Fed. Cir. 2005); *see also AK Steel,* 344 F.3d at 1244-45 (same).

48. Similarly, where a patent's specification teaches away from a particular technique for practicing the invention, and the patent's claims nonetheless encompass that technique, the patent is invalid for lack of enablement. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1380 (Fed. Cir. 2007). "A reference may be said to teach away when a person of ordinary

skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path taken by the applicant." *In re Gurley,* 27 F.3d 551, 553 (Fed. Cir. 1994). "[I]n general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *Id.*

49. Section 112's enablement requirement can also limit the scope of the patent claims, as "[t]he scope of [patent] claims must be less than or equal to the scope of enablement." *Invitrogen,* 429 F.3d at 1070-71. The requirement that the specification enable skilled artisans to "make and use the full scope of the claimed invention" ensures that the invention can be used "as broadly as it is claimed." *Id.* (quoting *In re Goodman,* 11 F.3d 1046, 1050 (Fed. Cir. 1993)). Expansive claim language may not be supported under the section 112 enablement requirement merely by describing one embodiment of the thing claimed. *Lizardtech, Inc. v. Earth Resource Mapping, Inc.,* 424 F.3d 1336, 1346 (Fed. Cir. 2005).

7. The patents-in-suit are invalid for failure to name all of the correct inventors.

50. The parties will litigate whether the patents-in-suit are invalid for Wyeth's failure to join **REDACTED** a named inventor of the patents-in-suit because of

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51. Inventorship is a question of law with underlying factual issues. *See Board of Educ. v. American Bioscience,* 333 F.3d 1330, 1337 (Fed. Cir. 2003). Section 102(f) provides that "[a] person shall be entitled to a patent unless .. he did not himself invent the subject matter sought to be patented." 35 U.S.C. § 102(f). Accordingly, section 102(f) "makes the naming of the correct inventor or inventors a condition of patentability; failure to name them renders a patent invalid." *Pannu v. Iolab,* 155 F.3d 1344, 1349-50 (Fed. Cir. 1998). "All that is required of a joint inventor is that he or she (1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full

invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art." *Id.* at 1351.

8. If the preambles of the asserted claims limit claim scope, any claims of the patents-in-suit using the phrase "therapeutic metabolism" would be invalid for indefiniteness under Impax's construction of the claim term "a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma."

52. Had this Court adopted Impax's proposed construction of the claim term "a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma," and if the Court finds that the preambles of the asserted claims limit claim scope, the parties would have litigated whether the asserted claims of the patents-in-suit using the phrase "therapeutic metabolism" are invalid for indefiniteness.

53. A determination of claim indefiniteness is a legal conclusion that is drawn from the court's construction of the patent claims. *See Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005). Every patent specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112. Claims that are "not amenable to construction" or "insolubly ambiguous" are indefinite. *Datamize*, 417 F.3d at 1347. "[I]f reasonable efforts at claim construction prove futile," a claim term should be deemed indefinite. *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). Claims are *required* to be "sufficiently precise" so that a potential competitor may "determine whether or not he is infringing ... ." *Morton Int'l v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993). Where a claim fails this test, it is invalid. *See id.*

C. The patents-in-suit are unenforceable due to Wyeth's inequitable conduct during the prosecution of the relevant patent applications.

54. The parties will litigate whether the patents-in-suit are unenforceable because of Wyeth's inequitable conduct during the prosecution of the patents-in-suit. Specifically, the parties will litigate whether Wyeth made material misrepresentations to or withheld information material to patentability from the PTO during the prosecution of the patents-in-suit, and, if so,

whether Wyeth did so with the intent to deceive the PTO.

55. Under 37 C.F.R. § 1.56(a), "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [U.S. Patent and Trademark] Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." This standard applies not only to the named inventor(s), but also the prosecuting attorney or agent, and anyone else associated with the inventor or the assignee who is substantively involved in the preparation and prosecution of the application and extends throughout the patent's entire prosecution history. *See Fox Indus., Inc. v. Structural Preservation Sys., Inc.*, 922 F.2d 801, 804 (Fed. Cir. 1990).

56. A patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose information material to patentability or submits materially false information to the PTO during prosecution. *See Digital Control, Inc. v. The Charles Machine Works,* 437 F.3d 1309, 1313 (Fed. Cir. 2006). In other words, an inequitable conduct claim requires (1) a material omission or misrepresentation; and (2) intent to deceive. In evaluating the sufficiency of evidence, courts use a sliding scale that balances the evidence of each element. *See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997). "The more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa." *Pharmacia Corp. v. ParPharm, Inc.*, 417 F.3d 1369, 1373 (Fed. Cir. 2005).

57. A patent applicant's duty of candor and good faith is not limited to the disclosure of prior art. Instead, a patent applicant must disclose all material information to the PTO. *Critikon,* 120 F.3d at 1256; 37 C.F.R. § 1.56(a) (1992). Under this rule, "information is material to patentability when it is not cumulative to information already of record or being made of record in the application," and (1) a reasonable examiner would have considered it important in deciding whether to allow the application; (2) it establishes, by itself or in combination with other information, a prima facie case of unpatentability of any claim; or (3) it refutes, or is inconsistent with, a position the applicant takes in opposing an argument of unpatentability relied

on by the PTO, or in asserting an argument of patentability. 37 C.F.R. § 1.56(b); *Digital Control,* 437 F.3d at 1314-16. A withheld reference may be highly material if it discloses a more complete combination of relevant features, even if those features are before the patent examiner in other references. *See Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.,* 204 F.3d 1368, 1374 (Fed. Cir. 2000).

58. A reference is not immaterial simply because the patent claims are eventually deemed patentable thereover. *See Molins PLC v. Textron, Inc.,* 48 F.3d 1172, 1178 (Fed. Cir. 1995).

59. Intent to deceive the PTO "need not, and rarely can, be proven by direct evidence." *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.,* 394 F.3d 1348, 1354 (Fed. Cir. 2005). It "does not require a confession from the stand by the inventor or the prosecuting attorney." *See Hoffman-La Roche Inc. v. Promega Corp.,* 323 F.3d 1354, 1371 (Fed. Cir. 2003). Instead, intent may be inferred from the surrounding circumstances. *See Critikon,* 120 F.3d at 1256. Intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the application. *Id.* A lapse on the part of the patent examiner does not excuse an applicant's knowing omission or misrepresentation of material information. *KangaROOS U.S.A., Inc. v. Caldor, Inc.,* 778 F.2d 1571, 1576 (Fed. Cir. 1985).

60. In the absence of a credible explanation, intent to deceive is normally inferred from the facts and circumstances surrounding a knowing failure to disclose material information. *See Frazier v. Roessel Cine Photo Tech., Inc.,* 417 F.3d 1230, 1235-36 (Fed. Cir. 2005) (quoting *Bruno Indep.,* 394 F.3d at 1354). Applicants cannot overcome this inference with "[a] mere denial of intent to mislead." *Critikon,* 120 F.3d at 1257.

61. The fact of misrepresentation, along with proof that the party making it had knowledge of its falsity, is enough to warranty drawing the inference that there was a fraudulent intent. *See Lipman v. Dickinson,* 174 F.3d 1363, 1370 (Fed. Cir. 1999).

62. Implied notice of a fact is notice that is inferred from facts that a person had a

means of knowing and that is thus imputed to that person; actual notice of facts or circumstances is information that, if properly followed up, would have led to knowledge of a particular fact in question. *See Brasseler, U.S.A. v. Stryker Sales Corp.*, 267 F.3d 1370, 1382 (Fed. Cir. 2001).

63. To avoid a finding of inequitable conduct, doubts concerning whether information is material should be resolved in factor of disclosure. Where an applicant, his representatives, or others involved in a substantial way with the application knew of information, the materiality of which may be so readily determined, such people cannot intentionally or through gross negligence avoid learning of its materiality. If such a person does so, that is a basis for finding that the person should have known of the materiality of the information. *Brasseler,* 267 F.3d at 1380. Close cases should be resolved by disclosure, not unilaterally by the applicant. *See Critikon,* 120 F.3d at 1256.

64. An applicant, applicant's representative, or others involved in a substantial way with a patent application, cannot cultivate ignorance or disregard warnings that material information or prior art may exist merely to avoid actual knowledge of that information or prior art. Where one does, deceptive intent may be inferred. Once an applicant, representative, or other involved has notice that information exists that appears material and questionable, that person cannot ignore that notice in an effort to avoid a duty to disclose. *See Brasseler,* 267 F.3d at 1382.

65. A patent is unenforceable if, in bad faith or with deceptive intent, the named inventor(s) fails to correctly name all inventors. *See Frank's Casing Crew & Rental Tools, Inc. v. PMR Techs., Ltd.,* 292 F.3d 1363 (Fed. Cir. 2002).

66. Where information is material and the applicant, the applicant's representatives, or others involved in a substantial way with the application knew or should have known of the materiality, the applicant, representatives, and involved others will have great difficulty in establishing subjective good faith sufficient to overcome an inference of intent to mislead. *See Bristol-Myers Squibb,* 326 F.3d at 1239.

67. Inventors represented by counsel are presumed to know the law. *See Brasseler,*

267 F.3d at 1385.

D. Wyeth's remedies in the event the patents-in-suit are found valid and infringed.

68. If Wyeth's patents are found valid and infringed, the parties will litigate whether Wyeth is entitled to an order that "the effective date of any approval of" Impax's extended-release venlafaxine product "be a date which is not earlier than the date of the expiration of the patent which has been infringed. 35 U.S.C. § 271(e)(4)(A). The parties also will litigate whether Wyeth is entitled to injunctive relief against Impax "to prevent the commercial manufacture, use, offer to sale, or sale within the United States or importation into the United States of" Impax's extended-release venlafaxine product. 35 U.S.C. § 271(e)(4)(B).

69. The grant or denial of a permanent injunction is within the equitable discretion of the trial court. *eBay, Inc. v. MercExchange, LLC,* 126 S. Ct. 1837, 1839 (2006). "According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *Id.* "These familiar principles apply with equal force to disputes arising under the Patent Act." *Id.*

E. This is not an exceptional case, and Wyeth is not entitled to its attorneys' fees.

70. Under 35 U.S.C. § 285, "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party" in patent-infringement cases. "Among the types of conduct which can form the basis for finding a case exceptional are willful infringement, inequitable conduct before the P.T.O., misconduct during litigation, vexatious or unjustified litigation, and frivolous suit." *Hoffman-LaRoche, Inc. v. Invamed, Inc.,* 213 F.3d 1359, 1365 (Fed. Cir. 2000) (quoting *Beckman Instr., Inc. v. LKB Produkter AB,* 892 F.3d 1547, 1551 (Fed. Cir. 1989)).

EXHIBIT F

Tab F has been redacted in its entirety.

EXHIBIT G

EXHIBIT G

REDACTED IN ITS ENTIRETY

EXHIBIT H

TAB H

Plaintiff's List of Witnesses to Be Called Live or by Deposition

Plaintiff Wyeth expects to call some or all of the witnesses identified below either live or by deposition (transcript or video). This list is not a commitment that any of the witnesses listed are available or will appear for trial. To the extent that a witness's circumstances change, or a witness otherwise becomes unavailable for trial, Wyeth reserves the right to call that witness by deposition or to call a substitute witness. Wyeth further reserves the right to call: (1) one or more additional witnesses whose testimony is necessary to establish authenticity or admissibility of any trial exhibit if the admissibility of the exhibit is challenged by Impax; (2) additional witnesses to respond to issues raised by the Court's pretrial or trial rulings or to issues raised after the submission of this witness list, such as testimony of witnesses who have not yet been deposed; (3) any witness live for impeachment purposes; and (4) any witness who appears on Impax's List of Witnesses, attached hereto as Tab I.

The following is a list of witnesses whom Wyeth may call at trial, either in person or by deposition. Where a listed witness is a current Impax employee, the address given is Impax's principal place of business:

Joseph M. Mahady (live)
Wyeth
500 Arcola Road
Collegeville, PA 19426

Dr. Eliseo Salinas (live)
Shire Pharmaceuticals
725 Chesterbrook Blvd.
Wayne, PA 19087

Peter Hunter (by deposition)
IMS Health Inc.
960 Harvest Dr., Bldg. C
Blue Bell, PA 19422

Charles Hsiao (live or by deposition)
Impax Laboratories, Inc.
30831 Huntwood Avenue
Hayward, CA 94544

Christina Leung (live or by deposition)
Impax Laboratories, Inc.
30831 Huntwood Avenue
Hayward, CA 94544

Mark C. Shaw (live or by deposition)
Impax Laboratories, Inc.
30831 Huntwood Avenue
Hayward, CA 94544

Lee Foong Siew (live or by deposition)
Impax Laboratories, Inc.
30831 Huntwood Avenue
Hayward, CA 94544

Laura A. Williams (by deposition)
P. O. Box 873
Gardiner, Montana 59030

Gary Liaw (by deposition)
Impax Laboratories, Inc.
30831 Huntwood Avenue
Hayward, CA 94544

Impax Laboratories, Inc.
30831 Huntwood Avenue
Hayward, CA 94544
By: Theodore Smolenski (by deposition)

Deborah M. Sherman (live or by deposition)
Wyeth Research
641 Ridge Road
Chazy, New York 12921

Dr. Lynn A. Cunningham (by deposition)
Cunningham Clinical Research
102 Rottingham Court #2
Edwardsville, IL 62025-3686

Alza Corporation
1900 Charleston Road
P. O. Box 7210
Mountain View, CA 94043
By: David Edgren (Rule 30(b)(6) designee) (by deposition)

Richard DeNeale (by deposition)
3221 Essex Rd.
Willsboro, NY 12996

Xin (Joy) Li (live)
Wyeth
500 Arcola Road
Collegeville, PA 19426

Wyeth may also call one or more witnesses to establish the authenticity and/or admissibility of trial exhibits to the extent that Impax challenges the admissibility of such trial exhibits.

In addition, Wyeth may call the following expert witnesses live at trial. The subject matter of the testimony of each of these expert witnesses and their areas of expertise are set forth in their expert reports that have been served in this case:

Dr. Eric Hollander (live)
The Mount Sinai School of Medicine
Department of Psychiatry
One Gustave L. Levy Place, Box 1230
New York, NY 10029

Dr. James W. McGinity (live)
University of Texas at Austin
College of Pharmacy
2409 University Avenue
Austin, TX 78712-1074

Dr. Ronald J. Sawchuk (live)
University of Minnesota
College of Pharmacy
308 Harvard Street, S.E.
Minneapolis, MN 55455

Dr. Ronald A. Thisted (live)
The University of Chicago
Department of Statistics
5734 University Avenue
Chicago, IL 60637

Dr. Dhiren R. Thakker (live)
Division of Drug Delivery and Disposition,
School of Pharmacy
University of North Carolina at Chapel Hill
Chapel Hill, NC 27599

Dr. Henry G. Grabowski (live)
Duke University
Department of Economics
305 Social Sciences, Box 90097
Durham, NC 27708-0097

Wyeth reserves the right to call Richard A. Killworth as an expert in Patent Office Practice and Procedure should the Court permit Impax's purported patent law expert, Mark E. Nusbaum, to testify. Wyeth has moved to strike the expert reports of Mr. Nusbaum.

EXHIBIT I

WITNESSES IMPAX INTENDS TO CALL IN PERSON

Impax presently intends to call the witnesses identified below to testify in person at trial, or by deposition if those witnesses are unavailable. Impax reserves the right to call any witness identified on Wyeth's witness list.[1]

A. Fact Witnesses

Dr. Robin Enever	Wyeth Five Giralda Farms Madison, New Jersey 07940
Dr. Charles Hsiao	Impax Laboratories, Inc. 30831 Huntwood Avenue Hayward, California 94544
Deborah Sherman	Wyeth Five Giralda Farms Madison, New Jersey 07940
Ted Smolenski	Impax Laboratories, Inc. 30831 Huntwood Avenue Hayward, California 94544

B. Expert Witnesses

Dr. William S. Comanor	Economic Associates 4141 LaSalle Avenue Culver City, California 90232

Dr. Comanor is a Professor of Economics at the University of California, Santa Barbara and a Professor of Health Services at the School of Public Health at the University of California, Los Angeles. At UCLA, he founded the Research Program on Pharmaceutical Economics and Policy, where he is currently the Director. His writings on the economics of research and development in the pharmaceutical industry dates from the completion of his dissertation in 1963. He received his Ph.D. in economics from Harvard University in 1964. In 1965-66, he

[1] Impax has made its best efforts to provide herein the current addresses of current or former Wyeth employees. Those addresses are better known to Wyeth than Impax.

served as Special Economic Assistant to the Assistant Attorney General in charge of the Antitrust Division of the United States Department of Justice. Following that, he served as Assistant and Associate Professor of Economics at Harvard University and Stanford University. In 1975, he joined the faculty of the University of California. From 1978-80, he took a leave from his faculty position to serve as Director of the Bureau of Economics at the Federal Trade Commission in Washington, D.C., where he supervised a staff of over 200 employees, including more than 85 economists. His staff was responsible for providing economic support for all Commission activities as well as for carrying our economic research activities that dealt with competition issues. In April 2003, he was awarded the Distinguished Fellow Award by the Industrial Organization Society. That award is given annually in recognition of excellence in research, education, and professional leadership in the field of industrial organization. During his career, he has studied, lectured, written, and consulted extensively on issues dealing with the pharmaceutical industry.

Dr. Comanor may testify as to the absence of a nexus between the commercial success of Wyeth's Effexor® XR product and the invention claimed in Wyeth's United States Patent Nos. 6,274,171, 6,403,121, and 6,419,958 ("the Wyeth patents" or "the patents-in-suit"). Dr. Comanor is expected to testify about some of the factors that can affect the demand for pharmaceutical products like venlafaxine. More specifically, he is expected to testify that the commercial success of Effexor XR® is largely the result of Wyeth's marketing and promotional activities, along with the well-known and inherent benefits of the active ingredient, rather than Wyeth's extended-release formulation.

Dr. Arthur Kibbe

Wilkes University
Box 111
Wilkes-Barre, Pennsylvania 18766

Dr. Kibbe is a pharmaceutical formulations scientist with over 35 years of experience in the fields of biopharmaceutics, pharmacokinetics, and pharmaceutical excipients. He is currently

a Professor of Pharmaceutical Sciences at Wilkes University in Wilkes-Barre, Pennsylvania, and a consultant to the pharmaceutical industry. He received his Ph.D. in pharmacy and pharmaceutics from the University of Florida in 1973. In addition to his teaching career, he has worked with the pharmaceutical industry in various capacities. He has served as Senior Director of Professional and Scientific Affairs of the American Pharmaceutical Association, and has chaired the Pharmaceutical Advisory Commission of the U.S. Food and Drug Administration. In these capacities and others, he has worked with, consulted about, and evaluated extended-release formulations of various pharmaceutical products. He was editor-in-chief of the third edition of the internationally-recognized reference text, *Handbook of Pharmaceutical Excipients,* and has continued on the steering committee for all subsequent editions. He has trained professional pharmacists and pharmaceutical scientists, including over a dozen Ph.D.s currently working as formulators in the pharmaceutical industry.

Dr. Kibbe is expected to testify on the validity of the patents-in-suit. Specifically, he will testify that Wyeth's extended-release venlafaxine formulation was obvious in light of the prior art, and lacks the required written description of any formulation containing any ingredients other than those used in Effexor XR®. He is further expected to testify in rebuttal to Wyeth's experts regarding the meanings or indefiniteness of certain claim terms, if Wyeth's experts are permitted to offer testimony on the meanings of such terms. He is further expected to testify about the generic drug industry and the requirements for FDA approval, labeling, and marketing of a bioequivalent generic drug.

Had this Court adopted Impax's construction of the claim term "extended release formulation," Dr. Kibbe also would have testified on infringement issues. Specifically, he would have testified that Impax's extended-release venlafaxine formulation does not literally infringe the Wyeth patents under Impax's proposed construction of the claim term "extended release formulation." He further would have testified about the lack of equivalence between the Wyeth formulation used in Wyeth's Effexor® XR product and the Impax formulation accused of infringement.

Mark Nusbaum

Nixon & Vanderhye, P.C.
11th Floor
901 North Glebe Road
Arlington, Virginia 22203-1808

Mr. Nusbaum is a patent attorney and a former examiner for the United States Patent and Trademark Office. He received a bachelor's degree in electrical engineering from the University of Maryland in 1969, after which he joined the PTO as an Examiner. He later received his J.D. degree from American University in 1974. While at the PTO, he received the authority to grant or deny patents over his own signature in 1975, became a Senior Examiner in 1977, and was appointed a Supervisory Patent Examiner in 1980. In that latter position, he was responsible for training examiners, reviewing examiner work product, granting or denying patent applications, and assisting junior examiners in making patentability decisions. In 1983, he was appointed Examiner-in-Chief and a member of the Board of Patent Appeals and Interferences, the quasi-judicial appellate body that hears appeals from decisions of primary examiners adverse to patent applicants. Mr. Nusbaum's work on the Board required a detailed understanding of patent claims and how they should be construed, as well as an understanding and application of the pertinent statutes, precedents, rules, and other regulations regarding the examination of patent applications. While on the Board, he participated in approximately 500 to 750 appeals. In 1986, Mr. Nusbaum left the PTO to become a member of the Nixon & Vanderhye intellectual-property law firm, where he specializes in all phases of patent application preparation and prosecution and has served as an expert witness in PTO practice and patent law in patent-infringement suits.

To the extent permitted by the Court, given Wyeth's pending motion to strike his testimony, Mr. Nusbaum is expected to testify regarding issues related to Impax's counterclaim for inequitable conduct by Wyeth in withholding material prior-art references from the PTO during prosecution of the patents-in-suit. Specifically, he is expected to testify regarding PTO standards and practices regarding examination of patent applications in light of prior art, and the application of those standards to the Wyeth applications that matured into the patents-in-suit.

Dr. Jon M. Riddle

Economic Associates
4141 LaSalle Avenue
Culver City, California 90232

Dr. Riddle is an Adjunct Assistant Professor at the School of Public Health at the University of California, Los Angeles. He received a Ph.D. in Economics from the University of California, Santa Barbara. Currently, he teaches microeconomic theory of the health sector and empirical methods for UCLA's Executive Master of Public Health (EMPH) program. He also teaches economics and finance courses at both UCLA and the University of California, Santa Barbara.

Dr. Riddle may testify as to the absence of a nexus between the commercial success of Wyeth's Effexor® XR product and the invention claimed in Wyeth's United States Patent Nos. 6,274,171, 6,403,121, and 6,419,958 ("the Wyeth patents" or "the patents-in-suit"). Dr. Comanor is expected to testify about some of the factors that can affect the demand for pharmaceutical products like venlafaxine. More specifically, he is expected to testify that the commercial success of Effexor XR® is largely the result of Wyeth's marketing and promotional activities, along with the well-known and inherent benefits of the active ingredient, rather than Wyeth's extended-release formulation.

Dr. Stephen R. Shuchter

University of California, San Diego
School of Medicine
2445 5th Avenue, Suite 402
San Diego, California 92101

Dr. Shuchter is a psychiatrist who is an Emeritus Professor of Clinical Psychiatry at the University of California, San Diego. He received his medical degree in 1969 from the University of Chicago. After an internship at Chicago's Michael Reese Hospital in 1969-70, he received training in general adult psychiatry at Yale University from 1970-73. He then spent two years in the U.S. Army Medical Corps, working as a psychiatrist with active-duty military, their families, and retirees at Madigan Army Medical Center. In 1975, he joined the full-time

psychiatry faculty of UCSD, where he worked as a full-time professor until taking emeritus status in 2006. For almost 30 years, he was the Director/Medical Director of UCSD's outpatient clinical psychiatry service, which was the major outpatient training site for all residents, in psychiatry as well as family medicine and neurology, in addition to medical students, psychology doctoral and post-doctoral trainees, social-work trainees, and marriage and family counselors. He has researched issues related to and conducted studies regarding spousal bereavement, trauma, and the treatment of depression, and has authored or co-authored two books, several book chapters, and numerous research papers and clinical articles. He has supervised the clinical work of over 300 residents who have spent at least a year at the UCSD clinic. His book, *Biologically Informed Psychotherapy of Depression,* was cited by the *Journal of Affective Disorders* as one of the 25 most important clinical books of the 1990s.

Dr. Shuchter is expected to testify regarding the historical use of antidepressants, up to and including Wyeth's Effexor® and Effexor XR® products, the psychopharmacologic treatment of depression and anxiety generally, and his clinical experience in prescribing Effexor® and Effexor® XR in treating depression and anxiety specifically.

Dr. Bertram Spilker

Bert Spilker & Associates, LLC
8004 Overhill Road
Bethesda, Maryland 20814-1145

Dr. Spilker is a pharmacologist and medical doctor with expertise in the formulation of pharmaceutical products, the evaluation of the results of clinical studies, and interactions between pharmaceutical companies and the U.S. Food & Drug Administration. He received his Ph.D. in pharmacology from the State University of New York in 1967, and received his medical degree from the University of Miami in 1977. After receiving his Ph.D., he worked for several pharmaceutical companies, including Pfizer, Philips-Duphar, and Sterling-Winthrop. After receiving his medical degree, he practiced medicine in Reston, Virginia and at the University of North Carolina in Chapel Hill. Between 1978 and 1993, he worked for Burroughs Wellcome Co.

as a Senior Clinical Research Scientist and then as Director of Project Coordination, designing clinical trials for pharmaceutical products and analyzing their results and preparing submissions to FDA, among other duties.

In 1993, he left Burroughs Wellcome to become Corporate Vice President of Chronimed, Inc. At Chronimed, he was responsible for starting up and managing Orphan Medical, a pharmaceutical company that was initially a division of Chronimed. In 1994, Chronimed spun off Orphan Medical into a separate company, which Dr. Spilker served as President. Between 1994 and 1997, Dr. Spilker successfully built Orphan Medical into a viable company, designing its pharmaceutical portfolio, developing and implementing regulatory strategies, building the company infrastructure, and managing the development of the company's products. By the time he left in 1997, Orphan Medical was a public company listed on the NASDAQ exchange.

Then, between 1998 and 2002, Dr. Spilker served as Senior Vice President for Scientific and Regulatory Affairs for the Pharmaceutical Research and Manufacturers of America ("PhRMA"), a trade association engaged in lobbying, policy development, and advice to the pharmaceutical industry. Since 2002, he has been the principal of Bert Spilker & Associates, which consults with pharmaceutical industry groups on scientific and regulatory issues. Since 1980, he has also served as an Adjunct Professor of Medicine at the University of North Carolina School of Medicine and a Clinical Professor of Pharmacy at the University of North Carolina School of Pharmacy. Since 1993, he has served as a Clinical Professor of Pharmacy Practice at the University of Minnesota School of Pharmacy. He has authored eight books and co-authored four others, and published well over 100 additional book chapters and articles.

Dr. Spilker is expected to testify regarding Wyeth's clinical trials of its extended-release venlafaxine formulation, Wyeth's statistical methodologies in analyzing data from those studies, the clinical significance of the findings from those studies, and Wyeth's use of those findings in its submissions to the FDA. Dr. Spilker is further expected to testify regarding the state of the art in the field of extended-release formulations of pharmaceutical products at the time Wyeth began developing Effexor® XR. Dr. Spilker is further expected to provide testimony regarding how to

determine whether a difference between two formulations of a drug are scientifically and clinically meaningful and the relative value of anecdotal evidence in evaluating that difference. Dr. Spilker is further expected to provide general testimony regarding FDA practice and procedures.

Dr. William E. Wecker

William E. Wecker & Associates, Inc.
505 San Marin Drive
Novato, California 94545

Dr. Wecker is a statistician and applied mathematician. He received a Ph.D. in statistics from the University of Michigan in 1972. From 1973 to 1983, he was an Assistant and then an Associate Professor in the Graduate School of Business at the University of Chicago. From 1984 to 1989, he was an Associate Professor and then Professor in the Graduate School of Management at the University of California, Davis. In 1990 he founded William E. Wecker and Associates, an applied mathematics consulting firm. From 1994 to 1998, he taught as Consulting Professor of Law at Stanford University. He is a member of the American Statistical Association, the Institute of Mathematical Statistics, and the Society for Risk Analysis. He has served as associate editor of the *Journal of the American Statistical Association* for four years and of the *Journal of Business and Economic Statistics* for eighteen years. During his career, he has published approximately 35 articles in statistical, mathematics, business, and economics journals.

Dr. Wecker is expected to testify regarding the accuracy of the claims in the specification of the Wyeth patents-in-suit regarding Effexor® XR having a statistically significant improvement in incidences of nausea over conventional Effexor, and the appropriate methods of analysis of data from Wyeth's clinical studies of Effexor® XR.

WITNESSES IMPAX INTENDS TO CALL BY DEPOSITION

Impax presently intends to call the witnesses identified below to testify by deposition at trial. Impax reserves the right to call any witness identified on Wyeth's witness list to testify by deposition.[1]

Lawrence Alaburda	Wyeth Five Giralda Farms Madison, New Jersey 07940
John Clark	Wyeth Five Giralda Farms Madison, New Jersey 07940
Dr. Lynn Cunningham	Cunningham Clinical Research 102 Rottingham Court #2 Edwardsville, Illinois 62025-3686
Dr. Richard DeNeale	c/o Wyeth Five Giralda Farms Madison, New Jersey 07940
David Edgren	Alza Corporation 1900 Charleston Road P.O. Box 7210 Mountain View, California 94039-7210
Dr. Robin Enever	Wyeth Five Giralda Farms Madison, New Jersey 07940
Dr. Richard Kavoussi	Wyeth Five Giralda Farms Madison, New Jersey 07940
Jack Lamer	Wyeth Five Giralda Farms Madison, New Jersey 07940

[1] Impax has made its best efforts to provide herein the current addresses of current or former Wyeth employees. Those addresses are better known to Wyeth than Impax.

Angela Lukin	Wyeth Five Giralda Farms Madison, New Jersey 07940
Richard Mangano	Wyeth Five Giralda Farms Madison, New Jersey 07940
Dr. Eliseo Salinas	Shire Pharmaceuticals 725 Chesterbrook Boulevard Wayne, Pennsylvania 19087-5637
Deborah Sherman	Wyeth Five Giralda Farms Madison, New Jersey 07940
Douglas Smith	Wyeth Five Giralda Farms Madison, New Jersey 07940
Steven White	Wyeth Five Giralda Farms Madison, New Jersey 07940

EXHIBIT J

Tab J has been redacted in its entirety.

EXHIBIT K

IMPAX'S BRIEF STATEMENT OF WHAT IT INTENDS TO PROVE AT TRIAL

In addition to the facts not in dispute, Impax intends to submit proof, or make offers of proof,[1] at trial showing that:

1. Had this Court adopted Impax's proposed construction of the claim term "extended release formulation," Impax's proposed extended-release formulation of venlafaxine would not literally infringe the Wyeth patents-in-suit.

a. Under Impax's proposed construction, the term "extended release formulation," as used in the patents-in-suit, means the specific combination of ingredients described repeatedly as "the invention" in the specification of the patents-in-suit: venlafaxine hydrochloride, microcrystalline cellulose ("MCC"), and, optionally, hydroxypropylmethylcellulose ("HPMC").

b. **REDACTED**

2. Had this Court adopted Impax's proposed construction of the claim term "extended release formulation," Impax's proposed extended-release formulation of venlafaxine would not infringe the Wyeth patents-in-suit under the doctrine of equivalents.

a. Although Impax's extended-release venlafaxine product is bioequivalent to Wyeth's Effexor® XR product under FDA regulations, Impax's product is formulated differently from the Wyeth product, and contains different ingredients that perform different functions in different ways to achieve different results.

b. Wyeth's Effexor® XR product is created through a process described in the specification of the patents-in-suit as "extrusion and spheronization." This process

[1] In light of the Court's recent claim-construction ruling, and in order to create a record in case of appeal, Impax also intends to make offers of proof regarding the evidence it would have presented regarding non-infringement and invalidity had the Court accepted Impax's proffered constructions of the disputed claim terms in the asserted claims of the patents-in-suit. In the interest of completeness, this list contains a description of Impax's offers of proof on such issues.

creates spheroids having a core composed of a pharmaceutically active ingredient mixed with a matrix former/binder. First, the active ingredient is mixed with a matrix former and binder (microcrystalline cellulose or "MCC") and with water to activate the binder and create an elastic mass that has a putty-like texture. Second, this wet, putty-like mass is processed through an "extruder," a machine which presses the material through small holes in a metal plate, creating strands of material, known in the art as "extrudate," that are shaped like short pieces of spaghetti. Third, the extrudate is placed in a "spheronizer," a machine consisting of a bowl with a grooved, rapidly rotating bottom. In the spheronizer, frictional forces break the extrudate into uniform pieces and rounds them off into spheroids. A coating that slows the dissolution of the spheroids is then applied. In this formulation, MCC is both a matrix former and a binder that is especially well-adapted for use in the extrusion and spheronization process, because it is both sufficiently elastic to be successfully extruded and sufficiently plastic to be successfully spheronized. The patents-in-suit suggest that hydroxypropylmethylcellulose ("HPMC") can be used in conjunction with MCC to manufacture spheroids.

c. By contrast, Impax's proposed product is created using a different process,

REDACTED

REDACTED

d.

REDACTED

e. The functions of MCC in the Wyeth formulation are (1) to provide a physical structure from which the venlafaxine is released during dissolution and (2) to help to slow the release of the venlafaxine into the body. MCC performs these functions by forming a matrix with the venlafaxine from which spheroids are formed. As explained above, the MCC and venlafaxine spheroids are then coated with an extended release coating.

f. In the Wyeth formulation, during dissolution, the dissolution and diffusion of the venlafaxine out of the MCC spheroid creates convoluted channels through the MCC spheroid. Molecules of venlafaxine move outward through the convoluted channels and come into contact with the extended release coating at a relatively low concentration. The venlafaxine then slowly diffuses through the extended release coating.

g. The result of using MCC in the Wyeth formulation claimed in the patents-in-suit is the creation of uniformly blended spheroids of MCC and venlafaxine (with optional HPMC) which may be coated with an extended release coating during manufacture and which, during dissolution, causes venlafaxine to reach the extended release coating at a relatively low concentration.

h.

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

3. Had this Court adopted Impax's proposed construction of the claim term "extended release formulation," Impax's proposed extended-release formulation of venlafaxine would not indirectly infringe the Wyeth patents-in-suit, either through inducing or contributing to the infringement of the patents-in-suit by others.

4. The Wyeth patents are invalid because they are anticipated by Patent Cooperation Treaty ("PCT") application No. WO94/27589 filed by Alza Corporation. Alza's PCT application expressly disclosed:

a. An extended-release venlafaxine formulation that was therapeutically effective in treating depression and "a method useful for antidepressant therapy by administering the controlled-release dosage form comprising the compound of the invention."

b. That the Alza formulation was intended to be administered orally and once a day to patients in need of antidepressant therapy.

c. That the Alza formulation achieved and maintained a desired concentration of venlafaxine in that patient's blood plasma, thus eliminating the peaks and troughs of blood-plasma concentration of venlafaxine associated with multiple daily dosing of conventional, immediate-release venlafaxine.

REDACTED

5. The Wyeth patents are invalid because they are obvious over prior art, including prior publications (including patents and patent applications, articles, meeting abstracts and poster presentations), public use, and public knowledge, in light of at least the following prior-art references and related facts:

a. U.S. Patent No. 4,535,186, issued to Wyeth in 1985, which teaches the existence of the chemical compound venlafaxine and its use as an antidepressant.

b. U.S. Patent No. 4,138,475, issued February 6, 1979, which describes an extended-release formulation technique used by Wyeth in its extended-release venlafaxine product, which technique involves creating spheroids comprised of an active pharmaceutical ingredient and microcrystalline cellulose ("MCC") through a process known as "extrusion and spheronization," coating those spheroids, and then placing the resulting coated spheroids in a capsule.

c. U.S. Patent No. 5,506,270, filed on January 30, 1995, issued on April 9, 1996, and assigned to Wyeth, which discloses the therapeutic efficacy of dosing patients once a day with extended-release venlafaxine.

d. The Patent Cooperation Treaty ("PCT") application No. WO94/27589, published by Alza Corporation on December 8, 1994, which discloses the therapeutic efficacy of delivering extended-release venlafaxine once a day to a depressed patient, in order to achieve and maintain a desired concentration of venlafaxine in that patient's blood plasma.

REDACTED

e. Wyeth's own experience in developing extended-release pharmaceutical formulations. **REDACTED**

Wyeth began its effort to develop extended-release venlafaxine by trying a known technique it had previously used—hydrogel tablets—and, when that failed, it switched to another known technique it had previously used—extrusion and spheronization—and succeeded **REDACTED** in developing a stable formulation that met its target dissolution profile. **REDACTED**

REDACTED

f. Wyeth's combination of these prior-art elements according to the known methods described above.

g. The predictability of the results of Wyeth's efforts to develop extended-release venlafaxine in light of the prior art:

- Dissolution profiles of all drugs are correlated with blood level profiles. Because of the similar physical and pharmacokinetic properties of propranolol and venlafaxine, one would expect that an extended-release dosage form of venlafaxine, with a similar dissolution profile to that of extended-release propranolol, would also give rise to a similar drug blood level profile and as a consequence a therapeutic level over the 24-hour dosage interval. Therefore a person of ordinary skill in the art would be confident in using the dissolution profile obtained for the propranolol extended release formulation as a target for the development of a venlafaxine extended release dosage formulation that would result in therapeutic blood levels.
- Because the extended release formulation of REDACTED was on the market, the dissolution profile of the extended release version of propranolol could be determined by purchasing the commercially available product and then evaluating it in a dissolution medium according to USP specifications for the dissolution of sustained release products. Because the dissolution profile is always expressed as a percentage of dose released over time, there would be no need to convert the profile between drugs.

This is the only reliable *in vitro* test that correlates with blood levels. One would assume that the blood level curve of REDACTED is the same as the desired curve for venlafaxine because both drugs have the same half-life.

REDACTED

- Further, a person of ordinary skill in the art would understand the nature of drug absorption throughout the gastrointestinal ("GI") tract. Most importantly, it has long been well known that the most efficient absorption occurs in the early parts of the small intestine. In addition, information available from the immediate release formulation of venlafaxine demonstrated that venlafaxine was efficiently absorbed in the stomach. The peak blood-plasma levels of immediate-release venlafaxine occur in 1.5 hours after administration, which matched the gastric residence time. Thus a person of ordinary skill in the art would expect that the delay of the dissolution of the drug caused by a controlled release formulation would not materially effect the efficiency with which the drug could be absorbed because absorption is more efficient in the intestinal tract than the stomach. If a dosage form releases the drug over six to eight hours, because of the transit time through the small intestine of up to 4 or 5 hours, the drug would be completely absorbed prior to leaving the small intestine. Taking

all this into account it is reasonable to expect that an extended release venlafaxine product would be completely absorbed, albeit over a longer time frame than the immediate-release formulation.

- A person of ordinary skill in the art would look at the normal transit time for oral solid dosage forms at between 6 to 8 hours (capsule and tablet gastric transit time and small intestine transit time) and the target of a peak of between 4 to 8 hours and realize that the target for the peak levels of the drug after administration of the extended release dosage form is very broad, indeed comprising almost half of the total time the dosage form spends in the part of the GI tract where absorption is most efficient.
- These target blood plasma levels, including the times to peak, are obvious. A person of ordinary skill in the art would have known about the physical properties and therapeutic effectiveness of venlafaxine from the immediate-release product, including its rate constant for elimination. One would be able to use this information with the appropriate pharmacokinetic model (in this case a one compartment model) to develop a theoretical blood plasma curve. That person could have used that knowledge (1) to determine when an extended-release formulation would need to reach peak blood-plasma levels in order to be therapeutically effective, and then (2) estimate the dissolution profile that would most likely achieve that blood level profile. At that point, a person of ordinary skill in the art would expect that the tested extended-release formulation would be therapeutically effective because it had matched the simulated performance of the product. Essentially, any person of ordinary skill in the art had sufficient

information, based on the performance of the immediate-release product, to model and create an extended-release product, and would have had an expectation of success in doing so.

REDACTED

- Because a target dissolution profile is developed based on known calculations and characteristics of the API, as discussed above, dissolution profiles in and of themselves are not inventive.

REDACTED

- A person of ordinary skill in the art would expect a flattening of the troughs and peaks of any extended release formulation of venlafaxine hydrochloride when compared to an immediate release formulation. As can be easily calculated, a decrease in the rate of absorption of a drug will cause a decrease in peak plasma levels and a delay in the time to peak.
- As a general matter, reducing the number of doses given to a patient over a 24-hour period inherently reduces the number of peaks and troughs in blood plasma levels. When a patient receives a dose of a drug in any formulation, the patient's blood plasma concentration of the active ingredient increases. Indeed, this increase is the very reason the dose was administered. Each such increase causes a peak. After each peak comes a trough, as the drug is eliminated or metabolized. The trough is the lowest

point the plasma concentration reaches prior to the next dose. Thus, a person of ordinary skill in the art would understand that there is one peak and one trough associated with every dose administered to a patient.

- Accordingly, once-a-day dosing will cause one peak and one trough per day; twice-a-day dosing will cause two peaks and two troughs per day; and so on. Thus, every extended-release dosage form eliminates at least some peaks and troughs compared to an immediate-release counterpart, because extended-release dosage forms, by definition, are administered less frequently than immediate-release dosage forms. This is true under the Wyeth construction of the claim term "for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride" recently adopted by the Court.
- To the extent there is an association between side effects and the occurrence of peaks, however, a reduction in those side effects would be associated with any extended release formulation of venlafaxine over any immediate release formulation.

REDACTED

h. Wyeth's use of the techniques described above, which techniques were known to persons of ordinary skill in the art to have improved other pharmaceutical products in the same way by enabling the creation of therapeutically-effective once-a-day dosage forms.

i. Wyeth's application of the known techniques described above to a known product (venlafaxine) that was ready for improvement, because of the demand for a once-

a-day dosage form, to achieve predictable results in light of the prior art.

j. The benefits of once-a-day dosing, which were well-known in the market as of 1991. Persons of ordinary skill in the art knew, and Wyeth witnesses have admitted that Wyeth knew, that drugs given once a day, as opposed to multiple times a day, were likely to increase patient convenience and thus more likely to result in increased patient compliance with prescribed therapy.

k. The finite number of possible solutions to the problem of developing extended-release venlafaxine.

l. Wyeth's reasonable expectation it would succeed in developing an extended-release venlafaxine product when it began trying to do so.

REDACTED

m. The fact that the additional purported benefits set forth in the patent claims—diminished incidences of nausea and emesis and elimination of peaks and troughs of blood-plasma concentration associated with multiple daily dosing—would be inherent in any extended-release venlafaxine formulation.

REDACTED

6. No secondary factors, such as the commercial success of Effexor® XR, weigh against a finding of obviousness.

a. In particular, any commercial success enjoyed by Effexor® XR has no nexus with, and can in no way be attributed to, the alleged invention described in the patents-in-suit.

b. To the contrary, until very recently, Wyeth's patent on the underlying chemical compound venlafaxine hydrochloride has prevented any other entity from bringing a venlafaxine product to market.

c. Further, any commercial success enjoyed by Wyeth's Effexor® XR product is principally the product of Wyeth's marketing and advertising expenditures, and not any the invention described in the patents.

7. The patents-in-suit are invalid for lack of written description. The specifications of the patents-in-suit describe only an extended-release venlafaxine formulation consisting of venlafaxine hydrochloride, MCC, and, optionally, HPMC, and no other ingredients. Because the Court declined to construe the claims as limited to only those three ingredients, the patents-in-suit must be invalid for lack of written description of other formulations.

8. The patents-in-suit are invalid for lack of enablement.

REDACTED

9. The patents-in-suit are invalid for failure to name and join one of the inventors of those patents.

REDACTED

REDACTED

10. Had this Court adopted Impax's proposed construction of the claim term "a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma," and if the Court construes the preambles of the asserted claims as limiting claim scope, the asserted claims describing the "therapeutic metabolism" of venlafaxine would be invalid for indefiniteness. That claim term is not used by persons having skill in the art and has no meaning to such persons. Wyeth's pharmacokinetics expert conceded that he had never used the term in his career outside the context of this litigation.

11. Wyeth engaged in inequitable conduct in prosecuting the patents-in-suit, and accordingly that those patents should be unenforceable against Impax for the following three reasons:

a. The specification of the patents-in-suit makes the claim that, in two eight-week and one 12-week clinical studies, Wyeth's extended-release venlafaxine product showed a statistically significant improvement in incidence of nausea over conventional immediate-release venlafaxine. This was an unsolicited argument for patentability by Wyeth over the prior art describing the therapeutic benefits of immediate-release venlafaxine and methods of formulating extended-release pharmaceutical products. Impax intends to prove that this statement is false and was intended to mislead the PTO, for the following reasons:

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REDACTED

REDACTED

- **REDACTED**

- To the extent Wyeth claims that the statement in the patent specification was intended to mean that the pooled results of the three studies showed the claimed reduced incidence, the specification does not mention pooling.
- More importantly, however, there is no statistically-valid basis for pooling the results of the three studies.

REDACTED

- Wyeth failed to disclose to the PTO the results of the three clinical studies that would have shown the statement in the specification to be false.
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REDACTED

REDACTED

d. Wyeth's intent to deceive the PTO is further demonstrated by its statement in the patent specification that "It was completely unexpected that an extended release formulation containing venlafaxine hydrochloride could be obtained because the hydrochloride of venlafaxine proved to be extremely water soluble." This statement is directly contradicted by Wyeth's internal correspondence regarding its expectation to succeed in developing extended-release venlafaxine.

12. If the Wyeth patents are found valid and infringed, Wyeth is not entitled to a permanent injunction barring Impax from making, using, offering for sale, selling its proposed extended-release venlafaxine product in the United States, or importing that product into the United States.

13. If the Wyeth patents are found valid and infringed, this is not an exceptional case entitling Wyeth to recover its attorneys' fees. Wyeth has not claimed willful infringement by Impax in this case, and Impax has committed no misconduct related to this case that could justify an exceptional-case finding and a fee award.

EXHIBIT L

TAB L

Wyeth's List of Miscellaneous Issues for the Pretrial Conference

Wyeth intends to raise the following additional issues at the Pretrial Conference.

1. In its pretrial submissions, Impax states that, to create a record in case of appeal, it intends to make an offer of proof regarding the evidence it would have presented on the issues of non-infringement and invalidity had the Court adopted Impax's proposed claim constructions. See, e.g., Impax's Statement of Issues of Fact to be Litigated, n.1. Wyeth contends that the trial should be conducted based on the Court's claim construction rulings, and that Impax should be precluded from attempting to conduct a parallel trial as if its rejected claim constructions had been adopted. Subject to the Court's approval, to resolve this issue, Wyeth proposes that both parties be permitted to reserve their right to introduce additional evidence on infringement and validity following any appeal from the Federal Circuit should the Federal Circuit adopt a claim construction that differs from this Court's construction.

2. In their respective claim construction briefing, both parties submitted to the Court preamble claim language to be construed. Impax in its pretrial submissions now contends that the claim preamble language should be given no effect. Wyeth submits that Impax's attempt to raise new claim construction issues is untimely, and has been mooted by the Court's claim construction. Therefore, Impax should be precluded from arguing that the preamble claim language should be given no effect.

3. In its pretrial submissions, Impax contends that if the patents-in-suit are found valid and infringed, Impax is entitled to litigate whether Wyeth is entitled under 35 U.S.C. § 271(e)(4)(A) to an Order that "the effective date of any approval of" Impax's extended release venlafaxine product "be a date which is not earlier that the date of the expiration of the patent

which has been infringed." Impax's Statement of Issue of Law to be Litigated at ¶ 68. Wyeth contends that if the patents are found valid and infringed, the Order required by 35 U.S.C. § 271(e)(4)(A) is mandatory, and not a matter of discretion for the Court.

Impax also contends that if the patents-in-suit are found valid and infringed, Impax is entitled to litigate whether Wyeth is entitled under 35 U.S.C. § 271(e)(4)(B) to injunctive relief "to prevent the commercial manufacture, use, offer to sale [sic, sell], or sale within the United States or importation into the United States of" Impax's extended release venlafaxine product. *Id.* Wyeth also contends that it is entitled to the injunctive relief referred to in 35 U.S.C. § 271(e)(4)(B). Should the Court conclude that such injunctive relief under the Hatch-Waxman Act requires a full *Ebay* analysis, then Wyeth requests that a separate hearing be scheduled following trial so that evidence relevant to a full *Ebay* analysis may be introduced.

4. Whether Impax's alleged patent law expert, Mark E. Nusbaum, should be permitted to testify as an expert witness at trial. Wyeth contends that he should not. Briefing is complete on Wyeth's motion to strike Mr. Nusbaum's expert reports (D.I. 275), including the supplemental briefing ordered by the Court at the November 9, 2007 motion hearing.

5. Wyeth and Impax disagree on the notice to be provided on the use of exhibits in the direct examination of non-adverse witnesses. Wyeth requests that by 7:00 P.M. one calendar day before the anticipated use at trial, a party be required to identify any such exhibits (demonstrative or otherwise) and any witness with whom the exhibits will be used. This notice provision would not apply to demonstrative exhibits created in the courtroom during testimony or to demonstrative exhibits that are merely excerpts, enlargements, or highlights of trial exhibits (if the trial exhibit has been identified to opposing counsel in accordance with this provision).

6. Whether paragraphs 72-73, 81-84, 129-130 and 133-136 of the rebuttal expert report of Dr. Arthur Kibbe should be stricken as untimely when the opinions offered in these paragraphs were offered well after the Court's deadline for Impax to offer opinions on validity of the patents-in-suit and at a point when Wyeth had no opportunity to respond. Briefing is complete on Wyeth's motion to strike those paragraphs of Dr. Kibbe's report (D.I. 295).

7. Wyeth proposes that a schedule be set for the filing and briefing of any motions in limine.

8. The procedure to be followed for the use at trial of Confidential and/or Highly Confidential documents or information of the parties or third parties.

EXHIBIT M

IMPAX'S STATEMENT OF MISCELLANEOUS ISSUES TO BE ADDRESSED AT THE PRETRIAL CONFERENCE

Impax hereby identifies the following miscellaneous issues to be addressed and resolved by the Court at the pretrial conference, or prior to trial of this case:

1. Whether this Court will hear motions *in limine*, and, if so, the appropriate briefing and hearing schedule on such motions.

2. Whether the parties will be permitted to present expert testimony on issues related to Impax's inequitable-conduct claim.

3. Impax's pending motion for summary judgment.

4. The pending motions to strike portions of the expert reports of Wyeth's experts Dr. Henry Grabowski and Dr. Ronald Thisted, and Impax's expert Dr. Arthur Kibbe.

5. The order of proof at trial, in light of this Court's December 13, 2007 ruling on claim-construction issues. Based on that ruling, Impax proposes that it begin trial by presenting evidence on the invalidity and unenforceability of the patents-in-suit, to be followed by Wyeth's rebuttal evidence on those issues.

6. The trial schedule, including the time allotted for each side.